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ROYAL COMMISSION OF INQUIRY INTO CERTAIN
DEATHS AT THE HOSPITAL FOR SICK CHILDREN AND
RELATED MATTERS.

Hearing held
8th floor
180 Dundas Street West
Toronto, Ontario

The Honourable Mr. Justice S.G.M. Grange

P.S.A. Lamak, Q.C.

E.A. Cronk

Thomas Millar

Commissioner

Counsel

Associate Counsel

Administrator

Transcript of evidence
for
January 25, 1984

VOLUME 92

OFFICIAL COURT REPORTERS

Angus, Stonehouse & Co. Ltd.,
14 Carlton Street, 7th Floor,
Toronto, Ontario M5B 1J2

595-1065



ROYAL COMMISSION OF INQUIRY INTO CERTAIN
DEATHS AT THE HOSPITAL FOR SICK CHILDREN
AND RELATED MATTERS.

Hearing held on the 8th Floor,
180 Dundas Street West, Toronto,
Ontario, on Wednesday, the 25th
day of January, 1984.

THE HONOURABLE MR. JUSTICE S.G.M. GRANGE - Commissioner
THOMAS MILLAR - Administrator
MURRAY R. ELLIOT - Registrar

APPEARANCES:

| | |
|----------------------|--------------------------------|
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| E. CRONK) | |
| T.C. MARSHALL, Q.C.) | Counsel for the Attorney |
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| L. CECCHETTO) | of Ontario (Crown Attorneys |
| | and Coroner's Office) |
| I.J. ROLAND) | Counsel for The Hospital |
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| | Children |
| B. SYMES | Counsel for the Registered |
| | Nurses' Association of Ontario |
| | and 35 Registered Nurses at |
| | The Hospital for Sick Children |
| H. SOLOMON | Counsel for The Ontario |
| | Registered Nursing Assistants |
| D. BROWN | Counsel for Susan Nelles - |
| | Nurse |

(Cont'd)...



APPEARANCES: (Continued)

| | |
|--------------------------------|---|
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| J.A. OLAH | Counsel for Janet Brownless - R.N.A. |
| B. KNAZAN | Counsel for Mrs. M. Christie - R.N.A. |
| S. LABOW | Counsel for Mr. & Mrs. Gosselin, Mr. & Mrs. Gionas, Mr. & Mrs. Inwood, Mr. & Mrs. Turner, Mr. & Mrs. Lutes, and Mr. & Mrs. Murphy (parents of deceased children) |
| F.J. SHANAHAN | Counsel for Mr. & Mrs. Dominic Lombardo (parents of deceased child Stephanie Lombardo); and Heather Dawson (mother of deceased child Amber Dawson) |
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| J. SHINEHOFT | Counsel for Lorie Pacsai and Kevin Garnet (parents of deceased child Kevin Pacsai) |
| V. NESLUND | Counsel for Dr. Buehler |



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E R R A T A

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(ANSWERS BY DR. BUEHLER)



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MT/ak

1
2 --- Upon commencing at 10:00 a.m.

3 THE COMMISSIONER: Mr. Roland, are
4 you on?

5 MR. ROLAND: Yes, Mr. Commissioner.

6 MR. LAMEK: Mr. Commissioner, I
7 wonder if I might say something before Mr. Roland
8 begins, please, and it goes to the scheduling of
9 witnesses.

10 As you know I had proposed that
11 immediately following the evidence going to the
12 report which we are now hearing, I thought that I
13 would call those persons most directly affected by
14 the report, and that had been our thought from the
15 beginning.

16 I have spoken to Mr. Strathy and to
17 Mr. Sopinka, and it is their preference I think
18 that their clients, at a rather later stage of
19 the proceedings, and with that I am perfectly happy
20 to agree.

21 Therefore what I am proposing, sir,
22 is that when this evidence is finished which it
23 appears now may be some time this week, I propose
24 next week to call certain nurses who were not on the
25 Trayner team. That is to say next week Nurse Costello
and perhaps Nurse Bell. To follow them with people



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like Mrs. Radojewski and Lynn Johnston and perhaps other nurses, and then to move on to the members of the Trayner team starting with Brownless, working through Christie, Scott, Nelles and Trayner, and that therefore is the revised proposed sequence of the evidence that I think will follow this.

THE COMMISSIONER: Is that the end of Part I?

MR. LAMEK: That will be the end of the evidence that I propose to adduce on Part I.

THE COMMISSIONER: You haven't heard any rumours, or have you from anyone else?

MR. LAMEK: I haven't yet, but perhaps we could at some appropriate time, perhaps towards the end of the week, raise the question of other evidence.

THE COMMISSIONER: If you feel you can indicate at any time what evidence you do intend to call. I take it you have not been asked by anyone to call any evidence other than what --

MR. LAMEK: Yes, I have had one request from counsel. I have discussed it with him and it is still in a state of uncertainty.

THE COMMISSIONER: Yes. All right. Thank you.



1
2
3 Well, we don't need to get too worked
4 up about it for a while.

5 Yes, Mr. Roland?

6 DR. LESBIA F. SMITH, Resumed

7 DR. JAMES WALTER BUEHLER, Resumed

8 DR. EVELYN MacKENZIE WALLACE, Resumed

9 MR. ROBERT KUSIAK, Resumed

10 CROSS-EXAMINATION BY MR. ROLAND:

11 Q. Let me start with for the
12 moment your methodology so that I understand it.
13 I gather from your report that this is - yes, I am
14 Ian Roland and I act for the Hospital - I gather
15 from reviewing the report that is what would be
16 termed a contract research project rather than
17 what is understood as a funded research where one
18 is competing for funds in doing certain kinds of
19 research, epidemiological research. That is there
20 wasn't with respect to your methodology any peer
21 review of the methodology before the studies took
22 place; the kind of peer review that would occur in
23 a funded research where you are competing for funds.

24 Is that fair to say?

25 (ANSWERS BY DR. SMITH)

A. It is fair to say this was
not a funded research endeavour.

Q. Yes.



1
2 (ANSWERS BY DR. SMITH)

3 A. And it was not peer reviewed
4 at that time that it was developed.

5 Q. So that I gather there was
6 no outside input into the methodology as you
7 developed it. The methodology was entirely done
8 by your group?

9 A. That is correct, yes.

10 Q. And in looking at the report
11 I see that there were no hypotheses established at
12 the outset. Rather it appears at least from my
13 review of the report that what you did is you
14 collected data through various studies, and then
15 having done that you describe the data that you had
16 collected in a descriptive fashion rather than
17 starting with a specific hypothesis and conducting
18 a study in a way to either establish or refute
19 these specific hypotheses.

20 A. There are various types of
21 epidemiologic studies. One of the ways of approaching
22 a situation is to do what is called a descriptive
23 study.

24 Q. Yes.

25 A. That is you describe what
happened, and from that derive some numbers that



1
2 (ANSWERS BY DR. SMITH)

3 you can then proceed to analyze.

4 Q. Yes.

5 A. There are also analytic
6 studies which are designed studies that help you
7 test a certain hypothesis.

8 Q. Yes.

9 A. So this particular report
10 covers both descriptive epidemiological techniques
11 as well as analytic techniques.

12 Q. Yes.

13 (ANSWERS BY DR. BUEHLER)

14 A. I believe in testimony given
15 yesterday we went through each section of the
16 report and addressed the questions that we were
17 asking at each section of the report.

18 Q. All right. Let's turn then
19 to some of the sections and in particular let's
20 start with Study No. 4 which is the ward population
21 study, and as I understand it you were dealing
22 there with a sample of 807 admissions and you told us
23 that you had originally 16 categories and 50 of those
24 807 admissions were given to Dr. Rowe and Dr. Freedom
25 to review (that is the information concerning those,
the specific information that you provided with



(ANSWERS BY DR. BUEHLER)

respect to each admission), and that there was no good agreement between them in their categorization of those 50 samples from the 807 admissions.

A. That is not precisely correct. The 50 that they looked at in attempting - during the process of putting this study together was not selected from that 807.

Q. I see. It was selected from the overall 2400, was it?

A. Partly, yes.

Q. I see. But apart from that I am right, am I, there was no good agreement on the 50, and then what you did I gather is you condensed the scale, I guess on Dr. Rowe's suggestion or with his assistance to three rather than 16 and then proceeded to let him do the categorization of the 807?

A. There were three categories for severity and three categories for prognosis.

Q. Yes.

A. (Dr. Smith) May I add? Each of these was subdivided into whether it was a medical or surgical admission.

Q. Yes.



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2

A. (Dr. Buehler) For prognosis.

3

A. (Dr. Smith) For prognosis.

4

Q. Isn't it fair to say usually

5

when you condense a scale rather than increasing

6

the reliability of the process of the study you

7

reduce the reliability of it? Isn't that a fair

8

statement? In other words, reducing from 16 to 3,

9

if anything, would reduce the reliability of it?

(ANSWERS BY MR. KUSIAK)

10

A. I'm sorry, I don't quite

11

understand what you mean by the word "reliability".

12

Q. Well, when you have 16 cate-

13

gories you can become - everything else being equal

14

you can provide a much more specific and reliable

15

categorization than you can from three broader

16

categories; isn't that so?

17

A. Well, by "reliable" you mean

a more precise estimate?

18

Q. Yes.

19

A. Rather than reliable in the

20

sense there is no misclassification of cases?

21

Q. Exactly.

22

A. Yes. I think the finer the

23

scale, given that the categories remain accurate

24

or the cases are put in their right category you

25



1
2
3 get a more precise answer.

4 Q. Yes. And when you have --

5 A. (Dr. Buehler) Let me add to
6 Mr. Kusiak's answer, please.

7 In addition to that I think as you
8 look at the methodology it is extremely important
9 to keep in mind the types of information that are
10 available to us, and the type of information that we
11 had for this part of the study was microfilm
12 discharge records that included certain patient
13 identification which we removed, patient's age,
14 a list of discharge diagnoses and a list of
15 procedures performed.

16 We worked with Dr. Rowe in putting
17 those categories together, and Dr. Rowe felt that
18 given the type of information that was available to
19 him that the three categories he used were the most
20 appropriate and best categories for that phase of
21 the study.

22 Q. Let me just read to you what
23 Dr. Rowe has testified to (and it is very brief) in
24 these proceedings about the categorization that you
25 asked him to do. And in particular with his view
of the kind of information that he was provided with.



1
2 This is in Volume 21 at page 3809 he
3 says - he was asked the question:

4 "Q. Were you comfortable performing
5 that exercise..."

6 (the exercise we are talking about)

7 "...with that kind of information?"

8 His answer:

9 "No.

10 Q. Why not?

11 A. Well, not really comfortable.

12 I was obliging the people who were
13 investigating because I felt they had
14 decided this was something they needed;
15 that we should do it. But we were
16 not invited into the planning of
17 that manoeuvre.

18 Q. Why were you uncomfortable
19 doing it?

20 A. Because of the limited
21 information that you would have
22 available to make a decision of
23 that sort.

24 Q. I take it what you would get
25 would be four lines that would
represent a file or a record in your



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"hospital that might be an inch thick?

A. Or more."

So it appears that Dr. Rowe, at least from the information that you provided to him (he was obliging you as he says), he didn't feel comfortable but it was sufficient information to do an accurate or a valid review of the 807 cases.

Now what do you have to say about that and what about the information that he was provided?



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(ANSWERS BY DR. WALLACE)

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A. Dr. Rowe did not express his sentiments to us. He said he would be happy to look at the information and do what he could with it. Where he found himself unable to make a judgment he indicated this ^{the} on/ slips of paper that were provided to him and these were withdrawn from the analysis.

I would also like perhaps to go into the background of why we adopted this particular methodology with which you are taking issue. Could I refer you to the last sentence on page 5. It begins:

"Similarly, it was not possible to divide the patient-day denominator into different age groups in order to calculate age-specific mortality rates."

Now, that is a very important sentence in this report. Having established that there was indeed an epidemic, that the mortality rates had increased, we were most anxious to establish whether these rates had increased for all age groups or only for specific age groups. Had we been given this information from the Hospital, which they did try to



B2

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(ANSWERS BY DR. WALLACE)

3

give us but were unable to do so, we would not then

4

have proceeded to do the study which we call Dr.

5

Rowe's study.

6

Q. You would have done an age-specific study as I understand it?

7

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A. Exactly, and we would have been able to say immediately whether the increase in the death rate was simply limited to younger children or was true for all children.

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A. (Dr. Buehler) Similarly, to add to what Dr. Wallace said, it was not possible to subdivide the patient-day denominator that we used in calculating mortality rates, using an indicator of severity of illness. These are issues that we explored in depth to the best that we could with members of the Hospital staff and the data were not available to subdivide patient days either by age or severity.

19

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22

A. So the study as designed was less than ideal, but given the circumstances we found ourselves in and the data sources that were available to us, this was the only way we felt we could reasonably try to answer the question.

23

24

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A. (Dr. Buehler) In addition, in



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(ANSWERS BY DR. WALLACE)

3

talking to Dr. Rowe about this part of the study,

4

we were very well aware that the information he

5

was being provided was certainly less than say the

6

information that Dr. Nadas was provided, as you

7

quite dramatically illustrated. I think we in

8

presenting the method state exactly what it was

9

that he had available.

10

Q. You see what concerns me

11

is that you have this assessment that there was no

12

good agreement between Dr. Rowe and Dr. Freedom in

13

the 50 or so cases that each of them did. What

14

concerns me is that the reason for that may not be

15

the categories which you condensed from 16 to 3, it

16

may be the paucity of information that each were

17

provided with, or the kind of information that each

18

were provided. It may be that their lack of good

19

agreement was found not in the categories but in

20

the information that each was assessing.

21

A. In that case it makes sense

22

to have only one person do the rating because he

23

would base his judgments on his own criteria.

24

Q. Yes but that might not be --
they may be

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the criteria may not be very subjective to that

individual if the information leads to a more



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(ANSWERS BY DR. WALLACE)

subjective rather than a more objective assessment,
objective in the sense that several cardiologists
would agree with him.

A. We would have to agree that,
yes, there was a great deal of subjective decision
making here, the study is less than ideal.

A. (Dr. Buehler) And to add to
that the advantage of having one observer make those
observations given the potential for variations of
non-observers was that one observer would be
consistent with himself.

Q. But nevertheless I take it
you didn't do any internal check to see if he was
internally consistent with his own?

A. That is correct.

Q. You didn't do that?

A. We didn't do that.

Q. You didn't do an external
check to see if he was consistent with some other
cardiologist?

A. We did not, no.

Q. And indeed as I understand
it, at least from your report, you didn't do a
comparison between the results achieved by Dr. Rowe



B5

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(ANSWERS BY DR. BUEHLER)

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even in examining those babies' deaths that he
examined during the epidemic period, or I think
there was one death that he examined outside the
epidemic period, with the results achieved by Dr.
Nadas for prognosis and severity?

7

A. We addressed
that issue yesterday and I think we emphasized
that the types of scores that Dr. Rowe and Dr. Nadas
performed were very different.

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Q. Except that they were both
doing essentially the same exercise when it came
to dealing with the deaths because Dr. Rowe did
deal with I think 16 or 17 deaths that fell into
the sample, and they were doing the same exercise
basically of trying to score severity and prognosis.
I am just wondering did you do any comparison of
those with the results achieved by Dr. Nadas to see
if there was any kind of accordance or agreement?

19

A. We did no
formal comparison of those.

20

21

22

Q. Can you tell us or recall your
informal comparison, when you say formal I take it
there was some comparison?

23

24

25

A. We -- well let



B6

(ANSWERS BY DR. BUEHLER)

me tell the reason we didn't do a formal comparison, and that was that the ratings that Dr. Rowe did were based on a sample of patients who began hospitalization on the cardiology ward, and therefore would not include all of the patients. The realm of patients who were at risk of death included patients who began hospitalization not only on the cardiology ward but also in other Hospital areas. So that there was some limitation to the population base from which Dr. Rowe's study was taken.

In addition we made no mathematical combination of any of Dr. Rowe's or Dr. Nadas' assessments. In other words, we didn't attempt to calculate rates using one assessment in the numerator and another in the denominator in this report. We were interested in looking at that in a very, very informal way, and I would qualify it as simply that, the overview that we made, but I cannot tell you how precise that was.

Q. Let's move on to Dr. Nadas for a moment. Maybe this came up yesterday, but just to deal with it shortly. I take it there was no age adjustment factor examined in Dr. Nadas' assessment, that is you didn't adjust his review for



B7

(ANSWERS BY DR. BUEHLER)

age. I put it that way because there may be implicit a greater degree of -- a greater chance of death with the same prognosis and severity for younger rather than older babies. We have heard that younger babies are more fragile. I wonder if there is anything in Dr. Nadas' study, any adjustment for age in that context.

A. Let me back up and say what Dr. Nadas' assessments were. Dr. Nadas' assessments were clinical assessments based on his view of the patient's chart, which included potentially all of the information that was in the chart, but obviously he must have focused his attention on certain parts of the chart, but we cannot speak to the specific reviews that he did since he is not here to testify.

Dr. Nadas as a clinician would take important factors into consideration and would most likely take age into consideration in making his assessments of patient severity, but I emphasize that we cannot speak for Dr. Nadas.

Q. So if there was any adjustment it was done by Dr. Nadas himself initially when he did his assessment?

THE COMMISSIONER: That is not



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(ANSWERS BY DR. BUEHLER)

an adjustment is it? What he is doing, he is looking
at the chart to make the answer, and it wouldn't
be a question of adjustment.



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THE COMMISSIONER: If I find a child who is age five days and has a certain disease, I might consider that more serious than a child that was five years with that disease, I don't know.

MR. ROLAND: Well, that is what I mean. By taking age into account you may have the same illness and the same clinical characteristics with respect to two children, but if one is substantially younger than the other it may be more severe with the younger rather than with the older.

DR. BUEHLER: Let me back up for a moment and address the issue of why Dr. Nadas was selected. I don't know if that is something that has come up prior to our testimony.

As has been presented, one of the early considerations that we had in making our assessments was the need for outside consultants, particularly the need for a cardiologist. As we are not here to -- certainly I am not qualified to assess Dr. Nadas' competence in making a clinical assessment. However, when the hospital recommended consultants to us Dr. Nadas was very, very strongly recommended and repeatedly so by the hospital staff, in particular by Dr. Carver. We were repeatedly told by Dr. Carver that Dr. Nadas is a pre-eminent pediatric cardiologist



1
2 and I think it was fair for us to assume that Dr.
3 Nadas is fully competent to make an informed
4 clinical impression of the severity of the illness
5 in a patient with heart disease.

6 MR. ROLAND: Q. I don't doubt that
7 for a moment. I am not in any disagreement with
8 you on that, I just wanted to know what the adjust-
9 ment exercise, if any, went on with respect to age
in his study and you have told me that.

10 (ANSWERS BY DR. BUEHLER:)

11 A. Okay. You have to separate
12 the process of making the assessment from the
13 process of analyzing the data.

14 Q. Yes.

15 A. Is that the question?

16 Q. Well, first of all, during the
17 assessment you have told us I gather that he did
18 adjust or you presume that he took age into
19 consideration when he was doing his assessment. Did
you do any adjustment in the analysis?

20 A. Okay, that is a separate
21 question, then.

22 Q. Yes.

23 A. In the analysis that we did of
24 the comparisons between deaths during the epidemic
25



(ANSWERS BY DR. BUEHLER:)

period and deaths not during the epidemic period we did not perform a multivariate analysis; in other words, the process of taking into account more than one variable at a time. If you are interested I could refer to my notes because some of that data is broken down by age.

Q. Yes. Well, for instance, what I am wondering is, did you do any kind of ranking, numerical ranking of the deaths by age, for instance, which would give us some sense of how the epidemic period compared to the non-epidemic period. The way in which, for instance, sports fan compare how one hockey team is doing to another by looking at the scoring statistics for each player on the team to see if there are - this wouldn't be the case this year, - a good number of Maple Leafs in the top ten in the scoring rates, that kind of numerical listing, scoring of hockey players. I wonder if you did that kind of numerical listing in the deaths by age for the babies.

A. (DR. BUEHLER) Mr. Kusiak?

A. (MR. KUSIAK) Did we do that?

Q. Which is a way, I gather, of giving some sort of qualitative analysis to the



(ANSWERS BY DR. BUEHLER:)

comparision between age and death or age and severity
of those babies who died.

A. I believe we have already
said in the analysis we have looked at the entire
group of the epidemic period deaths compared to the
group of non-epidemic period deaths in that manner
alone.

Q. Yes.

A. I think that is a point that
Dr. Haynes addressed in his report.

Q. Yes.

A. And if you are interested we
could get into that in more detail.

Q. All right. That is not in your
report, I take it, but you have done that kind of
work, looking at ranking them in that way.

A. Are you asking about the
performance of a specific type of statistical
test? It may be easier for us to answer your ques-
tion if you have the name of a specific test in
mind.

Q. Well, for instance, I am
thinking of the numerical ranking, did you do that
kind of thing; for instance, ranking them from the



(ANSWERS BY DR. BUEHLER:)

youngest to the oldest?

A. No. I believe we have already said that we looked at the group of epidemic deaths.

Q. Yes.

A. In comparison to the non-epidemic deaths as a whole.

Q. In the study 5 in doing the comparison of deaths you have told us that you checked the abstracting process carried out by the three members of your team and the fourth person and you did that by determining a level of concordance. What was the level of concordance that you were able to establish or find.

A. (DR. SMITH) It was over 90%. In crucial areas where the primary abstractor and the reviewing abstractor disagreed, those disagreements were discussed, reasons for them were explained and, for example, if one abstractor found something quite hidden in the chart that a reviewer had not found that fully justified that particular answer that they put on the abstraction sheet then that would be the final word.

A. (DR. BUEHLER) For specific areas of the abstracting form.



(ANSWERS BY DR. BUEHLER:)

Q. But overall it was 90%?

A. For the entire abstraction
form?

Q. Yes.

A. Not for the entire abstraction
form.

Q. I see, just for the key areas?

A. (DR. SMITH) For the key areas,
right.

Q. Now, let's turn to the associa-
tion of death with hospital personnel, which is your
section 8. As I understand it, Nurse Shielton, who
was a team leader, was used to compile the data from
various sources and one of the sources was known as
the Ward Information Statistics or WIN sheets; is that
correct?

A. (DR. BUEHLER) I'm not familiar
with that acronym.

Q. Well, let me show you the
sample of this. I gather that Nurse Shielton had a
number of data sources in which she compiled the
data. I wonder if this is one of the sources that
she had available to her. This is an example of the
WIN sheet that is kept by the hospital.



1
2 (ANSWERS BY DR. BUEHLER:)

3 A. There is one important excep-
4 tion, however, or distinction to make in that these
5 are xeroxes and Nurse Shielton used originals and
6 told us that in some cases the originals had hand-
7 written materials on the back. So, these are not
8 representative of the information that she used.

9 Q. All right. Well, did she have
10 the WIN sheets or these sheets available to her in
11 her work? This is for 1980, for instance, and it
12 was something kept by all of the wards. The example
13 I have handed up is a Ward 4A example and it shows
14 the shifts for the nurses that were on duty in those
15 days.

16 A. I cannot recall the exact
17 appearances of the sheets that she used and there-
18 fore I am unable to verify whether or not these are
19 the sheets she used.

20 Q. I see. The reason I asked this
21 is because there was I gather yesterday some question
22 about whether or not you had data available to you
23 about nurses being transferred in and out of the ward
24 during a shift. As I understand it, and correct
25 me if I'm wrong, as I understand it you indicated
you didn't think that data was available as part of
your data base and these WIN sheets show these



1
2 (ANSWERS BY DR. BUEHLER:)
3 nurses being transferred during a shift to other
4 wards and from Ward 4A. They don't show nurses
5 being transferred into 4A but they show nurses being
6 transferred out of 4A during a shift and the hours
7 they spent in some other ward. I wondered if this
8 was data that was available to you or used by Nurse
9 Shielton in providing the information she did to you.

10 A. I am not clear that I under-
11 stand your assumption of our response to the question
12 yesterday because I think it may not be exactly
13 correct. My understanding is that the information
14 that Nurse Shielton and it showed that there were
15 times when someone came on the shift at the middle
16 of the shift and sometimes there was a person who
17 started the shift and then left in the middle of the
18 shift. Clearly, if you look at the nursing calendar
19 that she constructed you see evidence of that, of
20 someone coming on mid-shift or some time after the
21 12 hour change.

22 Q. I see. We may be under
23 some misunderstanding and unfortunately I wasn't
24 here yesterday but I thought that you had indicated
25 I think when you were cross-examined by Ms. Symes
that there seemed to be a gap in the data to the



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(ANSWERS BY DR. BUEHLER:)

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extent that you weren't able to indicate or didn't
indicate if a nurse came on, for instance, Ward 4A
during a shift or left during the shift.

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(ANSWERS BY DR. BUEHLER)

A. Ms. Symes asked us, I believe, whether we could be certain that such changes were documented. We can't be certain that those changes were documented 100 per cent.

Q. You could only be certain if you documented them yourself I take it?

A. Pardon?

Q. I gather you could only be certain if you were there and documenting it yourself?

A. Documenting the comings --

Q. Documenting the comings and goings, yes.

A. Yes.

Q. Apart from that it is difficult to be certain about these things?

A. Yes, that is correct.

Q. You told us with respect to the work done by Nurse Shilton that you did some spot checking. You didn't check it all but you did spot check. Did you find any errors in your spot checks?

(ANSWERS BY DR. SMITH)

A. Miss Shilton's translations into our original calendar were immaculate. She was



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(ANSWERS BY DR. SMITH)

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a fastidious, meticulous worker, and we did not
4 find any errors. We did subsequently find other
5 transcription errors into our entries.

5

6

Q. I am talking about the first
stage.

7

A. At the first stage we did not.

8

9

Q. You have in your study given
us the association of deaths with Hospital personnel
10 during the epidemic period.

11

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15

Did you attempt to measure the
association of Hospital personnel and particular
nurses, because that is what is focused on in your
study, the association of nurses and deaths in other
periods, in non-epidemic periods, to see if you
could come up with the same kind of results?

16

(ANSWERS BY DR. BUEHLER)

17

A. This study that we performed --

18

Q. Yes.

19

A. -- with the nursing calendar
was limited to that nine-month epidemic period.

20

21

Q. Yes. Did you do any other
studies that tried to compare that, a similar study
to compare it to non-epidemic periods?

22

23

A. We did not do a similar study

24

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(ANSWERS BY DR. BUEHLER)

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for non-epidemic periods.

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Q. All right. Let me take you

now to your Table 11 so that I understand it and

deal with the confidence limits. First with

Nurse 401, as I see it, the confidence limits (this

is on page 44; these are for Category A deaths) is

23 to infinity.

As I understand it then that means
that in 95 - there is a 95% confidence that a death
will occur relative to other nurses 23 times to
infinity while Nurse Trayner or Nurse 401 is on
duty.

(ANSWERS BY MR. KUSIAK)

A. Would you repeat that relative
to...?

Q. Relative to the other nurses,
to the other staff.

A. The relative risk is the rate
of dying while Nurse 401 is on duty as compared to
when she is not on duty.

Q. When she is not on duty,
all right. So there is 23% chance to infinity that
it will occur while she is on duty rather than when
she is not on duty?



Smith, Buehler
Wallace, Kusiak
cr.ex. (Roland)

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(ANSWERS BY MR. KUSIAK)

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A. No. It means that the rate of dying while she is on duty is 23 times the rate of dying while she is off duty.

6

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Q. And that is the lower limit, and it is infinity at the higher limit?

8

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A. That is true.

Q. And if we compare that to Nurse 402, Nurse Nelles, her range for the total is 4.2 to 14.3, and I note that there is no overlap there between Nurse 401 and Nurse 402?

12

13

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A. That is true.

Q. And I gather that means, and correct me if I am wrong, that Nurse 401 is statistically significantly different than any other nurse; that is Nurse 402 or any other, because there is no overlap between her and the other nurses? So that makes her significantly different in a statistical sense?

19

20

21

A. Well, I think again -- that would be suggestive of a statistically significant difference.

22

23

24

25

Q. Yes.

A. I think one would have to do a slightly different analysis to actually show



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(ANSWERS BY MR. KUSIAK)

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that in a reverse way.

4

Q. What sort of analysis would
you do?

5

6

A. I would do a sort of a 2 by 2
table analysis looking at when both nurses were
on duty and when deaths occurred when both nurses
were on duty as compared to when deaths occurred
when only one of the nurses was on duty, and then
classify their work schedules similarly --

9

10

11

Q. Yes.

12

A. -- and attempt to analyze,
compare the relative risks of dying that way.

13

14

Q. And that would establish
whether there is, in your mind I take it, whether
there was a significant statistical difference
between Nurse 401 and Nurse 402?

15

16

17

A. Or any other nurse.

18

Q. You say in your mind this
doesn't do it?

19

20

A. It is suggestive.

21

Q. Have you done -- you haven't
done that study?

22

23

A. No.

24

25

Q. Is it something you can do or



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(ANSWERS BY MR. KUSIAK)

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not? Do you have the information to do it?

4

A. Well, given that this data
is accepted as accurate, one can do it.

5

6

Q. Yes. Now let me turn for a
moment to the report done by Dr. Haynes and Dr.
Taylor on your report, and I take it you have now
had an opportunity to read it and digest it?

7

8

9

(ANSWERS BY DR. BUEHLER)

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A. We have read Dr. Haynes'
report. We have not performed the recalculation
that he suggests.

11

12

13

Q. Yes, but apart from that
I take it you have digested the report?

14

15

16

A. We have read it. It took
Dr. Haynes a long time to review our report, and
we certainly haven't had a comparable amount of
time to review his.

17

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Q. Let me just ask you about
the summary that he does at page i at the beginning
of the report and simply ask you if you agree or
disagree with the conclusions he arrives at on that,
beginning on that page, and let's start with No. 1
which deals with the association of Hospital
personnel and deaths.



D7

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(ANSWERS BY DR. BUEHLER)

He says:

"This association was statistically significantly stronger than for any other person studied and numerically much stronger than any other association discovered in any of the other studies described in the Report."

I take it you would agree with that?

A. Let me just take a moment to read that paragraph in detail.

Q. All right.

A. Do you mind if I read it out loud.

Q. No, not at all.

A. "If the data on nursing work schedules (Study VIII Association of death with Hospital personnel) are accepted as valid, then the deaths during the July 1980-March 1981 period were exceptionally strongly associated with the working periods of one specific nurse. This association was statistically significantly stronger than for any other



D8

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(ANSWERS BY DR. BUEHLER)

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person studied and numerically

4

much stronger than any other associa-

5

tion discovered in any of the other

6

studies described in the Report."

Now --

7

Q. Stopping there.

8

A. Yes. I believe the question

9

that you just asked of Mr. Kusiak dealt with the

10

first part of that second sentence.

11

Q. Yes.

12

A. "This association was

13

statistically significantly stronger

14

than for any other person studied..."

And I believe Mr. Kusiak just addressed that issue.

15

Q. Yes.

16

A. Dr. Haynes has used the

17

word "exceptionally", and that is a word that we

18

did not use.

19

Q. All right. What about the

20

latter part of it, "and numerically much stronger

21

than any other association discovered in any of the

other studies described in the Report"?

22

Do you agree or disagree with that?

23

A. I do not know exactly what

24

25



D9

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(ANSWERS BY DR. BUEHLER)

3

if any re-analysis of our data Dr. Haynes performed.

4

If he did perform any other analysis it suggests

5

that he calculated odds ratios or relative risk

6

estimates for, say, the case control study.

7

As our Report appears we did not
make those types of calculations, and to answer

8

that precisely we would need to go back and do the

9

analysis slightly differently to answer that issue.

10

Certainly I do not believe that --

11

well as far as Nurse 401 is concerned... Let me

12

stop there.

13

Q. Let's go to the next one.

14

A. Yes.

15

Q. No. 2. He introduces the
next four numbered paragraphs with the paragraph:

16

"All of the comments that follow

17

are based on associations of much

18

less strength than that above. They

19

should therefore be given pro-

20

portionately less weight in attempting

21

to understand the reasons for the

22

increase in mortality during the

23

July 1980-March 1981 period."

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Do you agree with that, first of all?

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D10

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(ANSWERS BY DR. BUEHLER)

A. I will trust Dr. Haynes' ability in assuming that he is correct in analyzing the information that we present in our Report.

You see my problem is I cannot tell you with certainty about the associations being "of much less strength than that above".

Q. Yes.

A. It depends on whether you look at Category A, B, C or all deaths, and since we did not calculate odds ratios and relative risk estimates -- excuse me, since we did not calculate odds ratios as an estimate of relative risk in the case control study I cannot answer that question precisely. Certainly there was a very strong association observed between a particular nurse and certain deaths.

Q. All right. Going on to No. 2 it says:

"There was increased utilization of the ICU during the July 1980-March 1981 period which may have placed an increased burden of severely ill patients on the wards. Whether this actually affected the wards, and if



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(ANSWERS BY DR. BUEHLER)

so, whether the infant room on
Ward 4A was affected are not established
in the Report."

Do you agree or disagree with that?

A. There was increased utiliza-
tion of the ICU during that period. "Established",
I would say that is a word with some certainty.

Q. Yes.

A. And I would agree that we
could not say with certainty that we established
whether this actually affected the wards, and if
so, whether the infant room on Ward 4A was
affected. Yes, I would agree with that sentence.

Q. All right. Let's go to 3.
Would you agree with that?

A. "There were increased numbers
of infant beds on the wards, parti-
cularly 4A, during the increase in
mortality..."

To be precise the increase in number of beds
occurred three months before the increase in
mortality.

Q. Yes.

A. "...in comparison with the



D12

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(ANSWERS BY DR. BUEHLER)

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preceding period..."

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Q. Okay. You have made that
point.

5

6

A. "...but not the following
period (when other adjustments may
have occurred in the care of
patients as a result of the investi-
gations into the mortality increase)."

7

8

9

10

Yes, I would agree with that.

11

Q. Not far to go; two more.

12

A. No. 4.

13

"There was clustering of deaths: a.
on Ward 4A..."

14

15

16

17

18

Yes, we observed that. Let me just refer to that
section of the Report. On page 14 and page 15,
at the bottom of page 14 we begin with the sentence,
the second sentence in that paragraph that begins
at the bottom of page 14:

19

20

"For pre-epidemic deaths, the loca-
tion at the reference time was Ward
4A..."

21

22

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Q. 5A.

A. I'm sorry.

"...Ward 5A for eight of the eleven



D13

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(ANSWERS BY DR. BUEHLER)

(72.7%), Ward 4A for two (18.2%),
and Ward 4B for one (9.1%). For
epidemic period deaths, the location
was Ward 4A for 29 of 36 (80.6%)
and Ward 4B for seven (19.4%)."

Then we give that information for Ward 4B and say --
we make a comparison between the pre-epidemic --
we make a comparison between non-epidemic and
epidemic patients only for those non-epidemic
patients who were not on Ward 5A, and we assign a
probability of $p = 0.04$, Ward 4A versus 4B for
epidemic versus post-epidemic deaths.



E/DM/ak

1
2 THE COMMISSIONER: May I interpret
3 just for a moment.

4 DR. BUEHLER: Yes.

5 THE COMMISSIONER: Isn't what
6 Dr. Haynes is saying here, is he is saying that of
7 those deaths that took place on the ward there was
8 a cluster of them, there was an emphasis on Ward 4A
9 first of all.

10 DR. BUEHLER: Yes.

11 THE COMMISSIONER: And then after
12 that in the infant room of 4A, and that is - I think
13 that is what Mr. Roland is asking you to agree with,
14 to agree with that.

15 DR. BUEHLER: Yes, during the
16 epidemic period there were more deaths on Ward 4A.

17 THE COMMISSIONER: And also more
18 in the infant room of Ward 4A as well.

19 DR. BUEHLER: The information on
20 the room at the time of death was less complete
21 than information on ward at time of death and that
22 difference although suggestive was not statistically
23 significant.

24 THE COMMISSIONER: If you look at
25 page 15:

"Of patients with a known room number,



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2
3 "the location was in Room 418 (the 4A
4 infant room adjacent to the nursing
5 station) for 22 of 27..."

6 It seemed to me that you, Doctor, are saying the
7 same thing, but perhaps I am wrong.

8 DR. BUEHLER: Yes, we are making
9 a comparison 22 of 27. Here we are comparing, well,
10 let me take a moment to --

11 DR. WALLACE: Can I ask the point
12 Mr. Roland was making, I am sorry I have forgotten.

13 DR. BUEHLER: It may not be
14 necessary to go into this in great detail. I think
15 Dr. Haynes states it with somewhat more certainty
16 than how we stated it, and again I don't know if
17 Dr. Haynes and Dr. Taylor did any further analysis
18 of our data, they certainly had the data available
19 to do that if they wanted to.

20 MR. ROLAND: Q. Let's deal with,
21 he says there was clustering of the deaths and we
22 are talking about the epidemic period of course,
23 you have already dealt with 4A and you have dealt
24 with the infant room of 4A. Although I think in
25 reviewing your report at page 15 it appears, at least
to me, that there is a clustering with respect to
both the infant room and the ward?



E3 1
2 (ANSWERS BY DR. BUEHLER)

3 A. That is correct. He used the
4 word clustering, I may be trying to read Dr. Haynes
5 too carefully, he does not in that summary attach
6 any statistical test to that. So, yes, looking at
7 that there is clustering.

8 Q. And with respect to the hours
9 as well, that has some statistical significance?

10 A. Yes, that is correct.

11 Q. And among the patients with
12 intravenous lines.

13 A. Now, I don't think we can
14 say among those patients who died with intravenous
15 lines was there clustering on Ward 4A or for a
16 particular room.

17 THE COMMISSIONER: I'm sorry, what
18 was that, you say you can't say there was a cluster-
19 ing of patients with intravenous lines? I thought
20 all of the patients except one, certainly of the
21 Class A and Class B had intravenous lines, isn't
22 that right.

23 DR. BUEHLER: Yes. The point we
24 made in the report was that the children who died
25 during the epidemic period were more likely to have
intravenous lines. The way I read this is that



1
2 there was a clustering among patients who had intra-
3 venous lines which is a slightly different way of
4 saying that.

5 MR. ROLAND: Q. You don't know
6 whether the ones who didn't die - have you any
7 figures on those, the ones who did not die had no
8 intravenous lines?

9 (ANSWERS BY DR. BUEHLER)

10 A. Only for the death room rate
11 comparisons.

12 THE COMMISSIONER: Yes, and I have
13 forgotten, what were they, what were those?

14 DR. BUEHLER: Let me check that.

15 MR. ROLAND: Q. If you turn to
16 page 15 where you deal with the IV line under the
17 heading "Other Therapeutic Measures" it seems to
18 be statistically significant where you find that:

19 "31 of 36 epidemic-period deaths versus
20 9 of 20 non-epidemic deaths had an
21 IV line at the reference time ($p=0.003$)."

22 A. That is correct, I am just
23 not certain that is exactly what is said by the way
24 that sentence is phrased. But clearly as you pointed
25 out patients who died during the epidemic period
when compared to patients who did not die during the



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(ANSWERS BY DR. BUEHLER)

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epidemic period were more likely to have an intra-
4 venous line.

5

Q. Having dealt with the facts

6

let's go to the conclusions of Dr. Haynes and

7

Dr. Taylor draw, and they say:

8

"These features narrow down the

9

possible causes considerably."

10

And do you agree with that, that is you were able

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to exclude a good many causes, it narrows, these

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factors narrow these things down considerably.

They go on to say:

13

"Specifically, the increased mortality

14

appears to have been mainly due to

15

events in the care of infants with

16

intravenous lines in the infant room

17

of Ward 4A during the July 1980 -

18

March 1981 period."

19

A. I believe that is slightly

20

stronger language than we used in our report,

21

particularly with respect to the phrase "in the

22

infant room". But in a general sense I would

agree with that statement.

23

Q. Finally we deal with the

24

mortality surveillance study, and he concludes:

25

E5



(ANSWERS BY DR. BUEHLER)

"The mortality surveillance study described at the end of the Report does not appear to us to be adequate to prevent recurrence of the problem." That is the problem that we see in this report of yours. Do you agree or disagree with that?

A. We did not provide a methodology for the Hospital to conduct surveillance.

Q. That is right, there is no model that you provided us with.

A. We - I think what we did do however, was to approach how you might begin to look at that type of problem if surveillance detected an increase, but we did not provide a methodology for surveillance.

Q. And you didn't test any particular model I take it?

A. (Dr. Wallace) I don't recall that we were asked to do that.

Q. Whether you were asked or not, I just asked you did you do it, you didn't test any particular model?

A. (Dr. Wallace) No, we did not.



E7 1
2 (ANSWERS BY DR. BUEHLER)

3 A. Well, let me qualify that,
4 however. For example, earlier in the testimony we
5 mentioned that within two or three days, or shortly
6 after arriving at the Hospital, in fact the first
7 weekend that we were there, we were able to take
8 information that the Hospital routinely collects
9 and using that generate a figure that resembled
10 Figure 3 in our report. So to that, and I believe
11 in our recommendations, we mentioned that there is
12 information the Hospital is already routinely
13 collecting that could be used as part of a surveillance
program.

14 Q. But you haven't I gather
15 developed a model or tested a model to see whether
16 it would be useful or not in certain circumstances?

17 A. We have not developed a
18 surveillance program for the Hospital.

19 Q. Indeed I gather, and correct
20 me if I am wrong, that there are very few of any
21 hospitals that have a mortality surveillance model
that they use?

22 A. I do not have any precise
23 information on this on which to base an answer to
24 that question. I think it extremely important to
25



E8 1
2 (ANSWERS BY DR. BUEHLER)

3 realize that in the recommendation section of our
4 report we were in no way intending to imply or
5 suggest that the Hospital was not doing something
6 it should. We were offering a recommendation that
7 I think would be useful to hospitals in general
8 in the future.

9 Q. Let me turn to page "vi" of
10 the summary of Drs. Haynes and Taylor and they
11 talk about loose ends in the data. I just want to
12 ask you whether or not you in fact tried to deal
13 with any of these loose ends that he refers to,
and if so what results you achieve?

14 A. Let me just read this paragraph:
15 "Although the conclusions outlined
16 above are of considerable strength
17 from an epidemiologic perspective,
18 there are some "loose ends" in the
19 data concerning who was directly
20 responsible for and actually deliver-
21 ing the care of the patients who
died,..."

22 Q. Stopping you there, did you
23 do any kind of study to measure that in any statis-
24 tical sense?
25



(ANSWERS BY DR. BUEHLER)

A. We did - let me look for a moment at the data sheets we used in the preparation of the Atlanta Report. For example we did look at which nurse signed off on the medication sheets for medication doses. In the comparison epidemic to non-epidemic deaths, or in looking at the epidemic deaths themselves, there was no pattern that clearly emerged from that.

To continue with the sentence:

"...whether more severely ill patients were specifically assigned to the staff most closely associated with the deaths,..."

We did not address that issue:

"...and whether the deaths were associated with the working schedules of staff other than those considered."

Q. I think you have answered that in your presentation about other staff.

A. Thank you.

Q. Okay. Finally, on having read Dr. Haynes' and Dr. Taylor's full report is there anything in it, and let us set aside their re-analysis because we don't know the accuracy of



1
2 (ANSWERS BY DR. BUEHLER)

3 the figures we are dealing with there. Is there
4 anything you take particular exception to?

5 A. I would be reluctant to go on
6 record making those types of judgment at this time.
7 I think in fairness to us that is a valid request.

8 Q. Well, if you do have any
9 particular exceptions that you develop when you
10 have more time to review it perhaps you could let
11 us know.

12 A. I would be happy to do that.

13 Q. We have been asked this
14 morning by the Commissioner, or through his counsel,
15 to decide whether we are going to call any evidence
16 or not, and I am not sure at this stage whether I
17 want to call Dr. Haynes or Dr. Taylor to testify
18 about their review because I don't know if there
19 is any issues for them to meet in their analysis.
20 If you think there are, or if there are, if you
21 will let us know if you could and we will consider
22 that.

23 THE COMMISSIONER: Do you think
24 you need equal time with Dr. Haynes? I don't know
25 how long he had to take your report apart.

DR. SMITH: Four months.



1
2 (ANSWERS BY DR. BUEHLER)

3 THE COMMISSIONER: I was going to
4 ask if you could do it a little sooner than that.

5 MR. ROLAND: To be fair to
6 Dr. Haynes, and this is not criticizing the panel,
7 but he did provide the panel with some earlier
8 review, I think in October or November, of I think
9 the paper they did, or a draft paper so that the
10 panel does not come to Dr. Haynes' analysis entirely
fresh.

11 THE COMMISSIONER: I wonder if
12 you could do it within a month, if you could let
13 us know within a month if you take any issue with
14 that, you can let us know by letter or any other
form.

15 DR. BUEHLER: May I talk briefly
16 with the attorney who is representing me?

17 THE COMMISSIONER: Yes, certainly.
18 (Off record discussion held between Ms. Neslund and
19 Dr. Buehler.)

20 THE COMMISSIONER: The eyes of the
21 world are upon you, if you would like to go outside?

22 DR. BUEHLER: We will have to defer
an answer to that question until the end of the day.

23 THE COMMISSIONER: Oh, all right,
24
25



1
2 that is certainly better than a month. All right,
3 Mr. Roland.

4 MS. CRONK: I don't think that is
5 the question he was referring to.

6 MR. ROLAND: I am being fed a
7 question but I don't quite understand it yet, so I
8 will have to defer for the moment.

9 MR. TOBIAS: Will it take you four
10 months?

11 THE COMMISSIONER: I wonder what is
12 the position as far as Mr. Sopinka and Mr. Strathy
13 are concerned?

14 MR. BROWN: We have no questions,
15 Mr. Commissioner.

16 THE COMMISSIONER: I see, there
17 is no problem there. Mr. Strathy will or will not
18 be available?

19 MS. FORSTER: Mr. Strathy is making
20 his final argument at trial right now and expects
21 to be here at noon.

22 THE COMMISSIONER: Then there is
23 no problem there at all. What about Mr. Percival?

24 MR. YOUNG: I spoke with
25 Mr. Percival last evening and upon reviewing the
evidence to date we find we have no questions of



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the panel.

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THE COMMISSIONER: All right. Then

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that solves some problems.

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M/PS

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2 Did Mr. Strathy give any indication
3 of how long he might be? He's not coming on until
4 after all these others.

5 MS. FORSTER: He expects to be a
6 minimum of two hours, sir.

7 THE COMMISSIONER: Yes. Well, that
8 solves I think Mr. Lamek's problem. He is moon-
9 lighting this afternoon. I didn't put it in the
10 contract that he couldn't.

11 Yes, how are you now?

12 MR. ROLAND: Well, I think I under-
13 stand the question. Let me try it again.

14 Q. On reviewing page vi beginning
15 with "The loose ends", one of the things we dealt
16 with was data concerning who was directly responsible
17 for the actual delivery of the care of the patients
18 who died and you indicated that you did do a statistical
19 analysis of the signing off of the digoxin medica-
20 tions. Is that how I understand your evidence? And
21 that you found no statistically significant result
22 from that study, that is, it didn't seem to point
23 to one individual or another.

24 (ANSWERS BY DR. BUEHLER:)

25 A. This was part of the Death/Death
Comparison Study. As you can imagine, we did collect



(ANSWERS BY DR. BUEHLER:)

huge volumes of data and it is difficult for me to remember the details of everything precisely, but my general impression is, or my general recollection is that we saw no pattern with respect to who signed off on medications similar to the pattern that we observed for who was on duty; in other words, the duty schedules were not specific to patient assignments.

Q. Do you mean by that that the data wasn't available or that it was available and you didn't find any one or more nurses or doctors as statistically significant in administering digoxin prescribed? I take it what you were looking to was the signed off administration of the drug.

A. Yes.

Q. And that indicates, I take it, who administered the drug.

A. That is correct. In terms of the Death/Death Comparison Study, there was no, as I recall, statistically significant association between particular individuals who signed off on given medications and deaths during the epidemic period.

Q. Yes, right. Thank you.



(ANSWERS BY DR. BUEHLER:)

THE COMMISSIONER: Yes. Well, then,
can I formally call on you, Mr. Brown?

MR. BROWN: We have no questions, Mr.
Commissioner.

THE COMMISSIONER: Mr. Young?

MR. YOUNG: No questions, Mr. Commissioner.

THE COMMISSIONER: Is it Ms. Solomon?
Do you have any questions?

MS. SOLOMON: No questions, Mr.
Commissioner.

THE COMMISSIONER: No questions. Mr.
Labow?

CROSS-EXAMINATION BY MR. LABOW:

Q. Good morning. My name is
Stephen Labow and we represent a number of the
parents of children involved in this. I only have
a few short questions.

Dealing with your recommendation on
the bottom of page 28 which you have just dealt with.
My question concerns the data that the hospital
actually kept. Do you know how long the hospital
had kept that kind of data?

A. (DR. BUEHLER) No, I don't.
The information that we used for construction of



1
2 (ANSWERS BY DR. BUEHLER:)

3 Figure 3 went back to January 1st, 1976. So that
4 at least as you look at the figures in our report
5 we can say that that data was available back to that
6 time but prior to that I cannot tell you that.

7 Q. Did you only use the available
8 hospital data in compiling Figure 3 or did you use
9 other data that you have obtained?

10 A. The data that we obtained in
11 compiling Figure 3 was based on information that we
12 obtained from the hospital.

13 Q. Do you know who kept that data?

14 A. We received information from the
15 Medical Records Department, the Admissions Depart-
16 ment, the Hospital Administration, the Cardiology
17 Department, the Pathology Department and, to be
18 honest, I cannot recall precisely whether it was
19 the Administration or Medical Records or Admissions
20 or another department that kept the information we
21 used in Figure 3.

22 Q. Now, do you know if the data
23 was used for any particular purpose?

24 A. I do not know exactly how the
25 hospital uses that information. Prior to our arrival
at the hospital we were made aware of an investigation



(ANSWERS BY DR. BUEHLER:)

that had been begun by a member of the hospital staff using information that the hospital collected. I believe that that investigation at the hospital had started, did not begin until after this event. So, I cannot speak to the types of uses the hospital put all of that information.

Q. Now, how specific was the data kept? For example, did it include time of death?

A. I do not recall. The key source of the information in Figure 3 was a document called the Monthly Death List and I do not recall whether or not that document had time of death.

A. (DR. SMITH) I do recall it did not have time of death. It had a numerical order on the left, 1 through 30 or 31, and the deaths occurring -- that would correspond to each day of the month -- and then the death occurring on that particular day for the month.

Q. And that was for all the wards in the hospital?

A. (DR. SMITH) And it had also a Ward of Death, as I recall, and it may have had some other column, but that would be the Monthly Death List and they did not have the time of death,



Smith, Buehler,
Wallace, Kusiak
cr. ex. (Roland)

as I recall it.

Q. Do you know if other than the Monthly Death List there was any other particular information kept recording deaths at the hospital?

A. (DR. BUEHLER) I believe that there was other information.

A. (DR. WALLACE) The Pathology Department obviously would maintain a list of the autopsies that they had done and we were able to use information from that, information from the Cardiology Department to cross check the hospital death list.

A. (DR. BUEHLER) It might be helpful to refer to a certain section of the report. If you look at page 5 we said that:

"Since the location of death within the hospital as defined on the monthly death report was sometimes in error ---"

THE COMMISSIONER: I haven't found this yet.

DR. BUEHLER: I'm sorry, it is...

MR. LABOW: It is in the middle of the paragraph beginning, "In addition..."

THE COMMISSIONER: Oh, yes, yes, thank



(ANSWERS BY DR. BUEHLER:)

you.

A. And to skip a bit:

"...monthly death reports were checked against records from the Departments of Pathology, Cardiology, Cardiac Surgery, and clinical computers to ascertain...the correct location of death as far as wards are concerned."

Those are the different departments that had some information on deaths that we used in our report.

Q. Now, prior to compiling Figure 3, did you compare all of these records to ensure that Figure 3 was accurate?

A. What we did was within a few days after arriving at the Hospital use the Monthly Death Report and Monthly Census Information to compile a graph that resembled Figure 3. We felt that it was very important that all of the deaths, that the location of deaths be defined as accurately as possible and that is why we cross checked with so many different references.

MR. LABOW: Thank you. I have no further questions.



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THE COMMISSIONER: Yes, thank you, Mr.

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Labow.

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Mr. Tobias?

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MR. TOBIAS: Thank you, Mr. Commissioner.

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CROSS-EXAMINATION BY MR. TOBIAS:

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Q. Good morning. My name is

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Warren Tobias and I act for the family of Jordan

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Hines. I believe in response to some questions that

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Mr. Lamek asked the day before last, and I am directing

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this question specifically to Dr. Buehler, you indicated

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that it was your information that in preparing his

13

information for the report Dr. Nadas focussed on

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what was in the chart and it was your impression

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that he ignored whatever digoxin information he

16

had at that time. Do I have that evidence correctly?

17

(ANSWERS BY DR. BUEHLER:)

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A. That is not quite correct.

19

The information that Dr. Nadas used in developing

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his assessments was the hospital chart. Now, I can-

21

not speak on behalf of Dr. Nadas in terms of

22

exactly what he looked at in the charts.

23

Q. All right. Do you know the

24

extent to which Dr. Nadas used post mortem digoxin

25

information?

A. In developing his assessments



(ANSWERS BY DR. BUEHLER:)

for us and because his assessments were based on the use of the hospital charts, it is possible that he may have had some of that information because it was in the chart but the types of impressions that we were asking for were clinical impressions based on the clinical pattern of death. That's what we were asking him to give us an assessment of.

Q. Right.

A. The clinical pattern of death as a clinician, what is your impression of the timing of this child's death, what is your impression of the pattern of this child's death.

Q. All right. Is it fair to say then that in coming up with his own analysis, given the terms of reference that you have just referred to, he would in effect be looking only at the information in the hospital chart and would therefore not be looking at information which may have become available many months later after death in terms of digoxin readings in preserved tissue?

A. That's right, we gave him the charts to make his assessments.

Q. And in fact that is what he was asked to do, was to give his impression as a



(ANSWERS BY DR. BUEHLER:)

clinician.

A. That is correct.

Q. Now, I take it that obviously he did not have an opportunity to see any of these children. Did he have an opportunity and did he take advantage of that opportunity, if so, to discuss the condition of particular children with the clinicians who were treating them at the relevant time?

A. No, his assessment was not based on interviews with the clinicians who were responsible for the care of the children, it was based exclusively on hospital charts.

Q. All right. Now, with respect to his own ratings.

A. Yes.

Q. I take it therefore that when he gives an opinion as to whether the death was expected and consistent with clinical condition what he is talking about is expected and consistent with clinical conditions as revealed by the chart by the child's condition while hospitalized.

A. That is correct.

Q. All right. By the same token I



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BM/PS:

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(ANSWERS BY DR. BUEHLER:)

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would take it then that in coming to his conclusion

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with respect to the mode of death being consistent

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with special concern regarding digoxin intoxication,

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he would be directing his mind again to the terminal

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events as disclosed by the chart.

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A. That's what we asked him to do.

9

Q. All right. And that would be

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looking for signs of digoxin toxicity which are

11

exhibited clinically such as vomiting and other

12

perhaps more specific characteristics, am I correct
in that?

13

A. We asked him to look at the

14

clinical pattern of death, correct.

15

Q. Okay, fine. Now, at page 13

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of the report there is a discussion regarding the

17

criteria for category A deaths and category B

18

deaths and I must admit that I find it slightly

19

confusing, I am hoping that perhaps you can help

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me. You indicate that with respect to category A

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the children would have had to exhibit any one of

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four particular characteristics, one of which was,

23

and I quote:

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"...mode of death scored 'consistent

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with special concern' regarding



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1
2 (ANSWERS BY DR. BUEHLER:)

3 possible digoxin intoxication by the
4 consultant cardiologist..."

5 And then in category B as I understand it, there
6 were two factors: the reference time having to be
7 between midnight and 6 a.m. and,

8 "...mode of death scored 'consistent'
9 with possible digoxin intoxication
10 but without any of the Category A
11 criteria;"

12 Now, do I have that right?

13 A. Yes.

14 Q. Okay. Now, what I am concerned
15 about is this. With respect to category B when you
16 say the child would have exhibited a characteristic
17 that the "...mode of death scored 'consistent' with
18 possible digoxin intoxication..." my question is
19 scored by whom, again, the consulting cardiologist
20 or the pharmacologist or the pathologist?

21 A. That was Dr. Nadas' score, the
22 consultant cardiologist.

23 Q. All right. So that in effect
24 Dr. Nadas looked at two different tests or, if
25 I can prioritize them, tests going to two different
levels and that there is a qualitative difference I



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(ANSWERS BY DR. BUEHLER:)

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take it then between the mode of death being scored

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consistent with special concern and, on the other

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hand, the mode of death being scored consistent

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with possible digoxin intoxication.

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25jan84 2 (ANSWERS BY DR. BUEHLER)

G
EMTrc 3 Do I confuse you and muddy the
4 waters --

5 A. I don't quite understand
6 that question.

7 Q. Let me try it this way. Is
8 it possible given the fact that it was Dr. Nadas
9 who was making the judgment on both things, is it
10 possible, for instance, that he might find that
11 there was a child whose death was not consistent
12 with special concern but whose death on the other
13 hand was consistent with possible digoxin intoxica-
tion?

14 A. Yes, that is correct.

15 Q. Yes. So there are two
16 different tests?

17 A. Actually there are three
18 levels to that question. One is the clinical
19 pattern of death was inconsistent to his impression
20 with digoxin intoxication; it could have been
21 consistent or consistent with special concern. So
22 there were three possible responses to that
23 question.

24 Q. All right. Well, my question
25 specifically is this: As you know I act for the



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(ANSWERS BY DR. BUEHLER)

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family of Jordan Hines.

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A. Yes.

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Q. If you look at Dr. Nadas' report with respect to Infant Hines, Dr. Nadas was of the opinion that his mode of dying was not consistent with special concern regarding digoxin intoxication. All right?

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THE COMMISSIONER: I'm sorry, which number is it?

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MR. TOBIAS: No. 057, I believe, Mr. Commissioner.

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THE COMMISSIONER: That is 02-57?

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MR. TOBIAS: 02-057. It appears at page 65 of the Report, and in particular that passage that I am most concerned with appears on page 66 of the Report.

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Q. And I see the consultant cardiologist scored the timing of death as expected and consistent with clinical status and the mode of death as inconsistent with digoxin intoxication.

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A. That is correct.

Q. All right. What I am getting

at is this: I take it then that with respect to



1
2 (ANSWERS BY DR. BUEHLER)

3 Category A I read from that that Dr. Nadas probably
4 would not have scored that death as consistent
5 with special concern. Do I have that correct?

6 A. Yes. He scored it -- his
7 impression of the clinical pattern of death was
8 that it was inconsistent with digoxin intoxication.
9 However, that baby is a Category A death I believe.

10 THE COMMISSIONER: Category A because
11 of the --

12 DR. BUEHLER: For other criteria,
13 yes.

14 MR. TOBIAS: Q. That baby is a
15 Category A death because he exhibits two of the
16 four criteria in that Dr. Kauffman scored him
17 3 on the 1 to 5 digoxin scale, and there was
18 concern expressed by Dr. deSa that the available
19 pathological findings did not fully explain the
20 cause of death.

21 Now for those reasons Hines is
22 Category A. We don't know whether he might have
23 fallen into Category B in that Dr. Nadas may have
24 made a finding that the death was "consistent with
25 possible digoxin intoxication".

Now do I have that correct or am I



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(ANSWERS BY DR. BUEHLER)

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reading too much into these categories?

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A. No, no. The way the categories are constructed if you have any one of these positive markers then you are Category A, so this is an example of a child who did not have a positive marker with respect to the timing of death, who did not have one of those positive markers with respect to Dr. Nadas' clinical impression of the mode of death --

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Q. Yes.

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A. -- but did have a positive marker based on Dr. Kauffman's score and Dr. deSa's assessment of the available pathology material but Dr. deSa felt in that case he -- I don't remember his exact words, but he felt he could not establish cause of death based on available pathology.

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Q. All right. This is the point I am driving at and I am trying to state it as succinctly as I can, because the last thing I want to do at this stage of the proceedings is to muddy the waters.

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You agree with me that there were two different tests, all right, regarding the mode



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(ANSWERS BY DR. BUEHLER)

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of dying, consistent with special concern regarding

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digoxin intoxication and consistent with possible

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dig. intoxication, and that those are two --

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THE COMMISSIONER: I think one is
just a matter of degree, is it not?

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DR. BUEHLER: Yes.

8

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MR. TOBIAS: Q. I believe it is
a matter of degree. Is it your understanding on

10

the reading of Dr. Nadas' report because he scored

11

death as inconsistent with digoxin intoxication that

12

the Hines death wouldn't fit into either of those
tests?

13

A. Yes.

14

Q. Okay.

15

A. If I understand your question

16

I think you are saying because he scored it

17

inconsistent he therefore did not score it con-

18

sistent or consistent with special concern.

19

Q. Right. Now that is on

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Dr. Nadas' review based upon the chart and upon
what he found clinically?

21

A. That is correct.

22

Q. Now you agree, however, that

23

because Dr. Kauffman scored the baby a 3, that

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Smith, Buehler
Wallace, Kusiak
cr.ex. (Tobias)

G6

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(ANSWERS BY DR. BUEHLER)

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obviously he had some concern in his own mind with
respect to digoxin involvement?

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A. Let us turn to the criteria
that Dr. Kauffman used. That my help.

6

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Q. All right. Fine.

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A. If you look at Dr. Kauffman's
appendix, Appendix 1, it is a three-page appendix,
we are looking at the top of the third page.

10

MR. TOBIAS: Page 56, Mr. Commissioner.

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THE COMMISSIONER: Yes, at the very
end of the report, yes.

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A. Rating 3: Patients given
this rating were characterized by (1) presence of
digoxin in exhumed and/or fixed tissues of patients
for whom digoxin was not prescribed; (2) a clinical
course not inconsistent with digoxin intoxication.

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That is Dr. Kauffman's impression
of the clinical course.

19

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Q. All right. In fact Dr.
Kauffman has been here and we have had the benefit
of hearing his evidence.

21

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A. Yes.

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Q. I take it that you probably
haven't been asked to read that evidence but I can



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(ANSWERS BY DR. BUEHLER)

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tell you that the evidence he gave here is indeed
consistent with the definitions he used in giving
a rating of 3 in that he did have some concern.

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Now the difference, if there is
one, between the conundrum of Dr. Nadas' view and
Dr. Kauffman's view I take it would be resolved in
part, and only in part, on the basis that Dr.
Kauffman was not asked to ignore the post mortem
findings of digoxin, and in fact had that very
present in his mind when he rated the baby.

12

Do you agree with that?

13

A. I wouldn't care to second-
guess Dr. Kauffman's thought process.

14

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Q. Okay. Fine. Let me go on.

16

THE COMMISSIONER: I wonder is it
the same subject?

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MR. TOBIAS: This would be an
appropriate time, Mr. Commissioner. I was about to
move into a different area.

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THE COMMISSIONER: Fine. We will take
twenty minutes.

22

--- recess.

23

--- on resuming.

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THE COMMISSIONER: Yes, Mr. Tobias.



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MR. TOBIAS: Thank you, Mr.

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Commissioner.

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Q. Just before the break I was addressing a question to the panel which I think in fairness involved a degree of speculation. I would like to rephrase the question so that it contains less of a speculative degree, and I would like to paraphrase the reference by indicating that I understand the rules and the restrictions under which Dr. Buehler is testifying; ergo I do not direct the question so much at him as I do to his colleagues on the panel.

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My question is simply this: We have evidence before the Commission already from one of your own consultants, Dr. Kauffman, that he had a very high degree of concern, and I am paraphrasing but I think accurately, with respect to the possible digoxin involvement in the death of Jordan Hines.

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Now without telling you what other witnesses have verified and echoed that same view, I can tell you that there is other evidence before the Commission from other experts which tends to verify that view.

23

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We know by virtue of his terms of



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2 reference and the entire scope of what he was
3 asked to do that Dr. Kauffman, by necessary
4 implication, was involved very deeply with post
5 mortem digoxin readings. And in fact in the
6 reference that was made before the break to his
7 Rating No. 3, that was one of the factors he took
8 into account.

9 Evidence has been given here that
10 with respect to Dr. Nadas he did not look speci-
11 fically at post mortem digoxin readings but looked
12 at it clinically only.

13 I would ask you to speculate to
14 this degree: the apparent inconsistency between
15 the view of Dr. Kauffman, his special concern with
16 digoxin involvement, and the view Dr. Nadas
17 expressed that the mode of dying was not consistent
18 with concern for digoxin toxicity, is one possible
19 explanation to that the very fact that by his
20 terms of reference Dr. Nadas was not looking at
21 the post mortem values?

22 (ANSWERS BY DR. WALLACE)

23 A. I feel really that we cannot
24 comment on what Dr. Nadas was thinking when he made
25 this decision.

Q. All right. Let me ask this



Smith, Buehler
Wallace, Kusiak
cr.ex. (Tobias)

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(ANSWERS BY DR. WALLACE)

and we will leave it there: Do we agree that in forming an opinion regarding the child's condition clinically one would have to be concerned with events during life as opposed to information which became available after death? Can we go that far? Can we agree on that?

A. Yes.

A. (Dr. Smith) Yes.

Q. All right. Thank you.

Now with respect to the discussions that occurred the day before last at Volume 90, and I am referring to pages 236 and 237 of the transcript, Mr. Commissioner - this goes to the question of the relative risk of death between Wards 4A and 4B.

I believe your evidence was that the relative risk of death with respect to those two wards was 4.1 with a 95% confidence limit, giving you a range of 2.1 to 6.0.

Now just so that I understand what the statistics stand for, am I correct that what that means is that the relative risk of death occurring on 4A was anywhere from 2.1 to 6.0 times higher on 4A than on 4B? Do I have that correctly?



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(ANSWERS BY MR. KUSIAK)

A. With a certain probability;
95% probability.

Q. Okay. Fine.

Now with respect to Ward 4B your
evidence was that there was a small increase seen
in the last three months of the epidemic, and that
the relative risk gave you a mean value of 1.5. Again
with the 95% confidence limit so that the range was
.7 to 3.2.

Now I take it by that you mean that
the relative risk of death occurring on Ward 4B
during the epidemic period was about 1.5 and the
range would have been anywhere from .7 to 3.2; is
that correct?

A. Yes, with 95% probability.

Q. Now I also understood your
evidence to be that because the low end of that
range was less than 1, you found that the rise in
death on 4B during that period was not statistically
significant.

A. Yes, at the 95% confidence
limit.

Q. So I think it is fair to
conclude from that that basically the epidemic you



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(ANSWERS BY MR.KUSIAK)

discovered and that you documented was particular
in fact to Ward 4A. Is that also correct?

A. The epidemic that we could
show was on 4A, yes.

Q. Now we are obviously con-
cerned here with babies who were treated on 4A/4B,
some of the deaths having occurred on 4B, and it
is obvious that the point of this exercise is to
enquire as to how and by what means those babies
came to their deaths.

My question to you is this: Even
though you found that the rise in deaths on 4B was
not statistically significant, does that factor in
and of and by itself mean that the same factors that
were occurring on 4A could not also have been
happening on 4B?

A. Well, again I deal with --
my business is probabilities, and the fact that
something is not statistically significant does not
mean there is no effect there.

Q. All right. Fine. And it
also doesn't mean that it can't happen I take it?

A. Paraphrasing it, yes.

Q. Okay. Fine.



Smith, Buehler
Wallace, Kusiak
cr.ex. (Tobias)

G13

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Now with respect to the conclusions to your report, I believe in the Conclusions section to the report there is a line, and I can't put my hands on it right now, but is it one of the findings of this study that in fact the epidemic period came to an end in March of 1981?

(ANSWERS BY DR. SMITH)

A. That is correct. We state that on page 28 of the report, at the beginning of the recommendations.

Q. All right. Now that comment obviously can assist us in no greater manner than the time frame during which your study covered. In other words I believe that the periods covered went to June 1982 or was it July 1982?

A. July of 1982.

Q. All right. So you make no comment on whether or not there was a similar phenomenon beyond July of 1982? Do I have that correct?

A. We don't make any statement about that beyond July 1982.

A. (Dr. Buehler) May I add to Dr. Smith's answer?



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Q. Yes.

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(ANSWERS BY DR. BUEHLER)

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A. We did, however, look at some deaths which occurred in July, August, September and October of 1982.

Q. Your conclusions were that that did not amount to an epidemic?

A. In response to the similar question that Mr. Lamek asked I believe yesterday, we did not pursue this to a similar extent and therefore I cannot say with certainty was there or was there not an epidemic.

We did, however, look at some of the patterns of death that occurred in July, August, September and October 1982 and based on that examination of those deaths our conclusion was that there was no clustering of deaths with respect to the particular time or ward as we observed during the period July 1980 through March 1981.



/DM/ak

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Q. Now, I believe, Dr. Buehler, that you gave evidence yesterday, and please correct me if I have misinterpreted this, that related to the death roommate study. I thought that what you were saying is that the children who died generally had more severe anatomical heart abnormalities than their roommates who did not die. Do I have that evidence correctly?

(ANSWERS BY DR. BUEHLER)

A. That is not correct. What we did say was that we used an indicator of nursing time required for care, and for those roommate survival comparisons where information was available. In most cases the child who died required more nursing time than the other children who were in the room at the same time that child suffered his or her terminal event.

Q. So that it doesn't necessarily then go to the anatomical problem?

A. That is correct. The way we had it it was an indicator of the nursing time required for the care of that child.

Q. I take it Jordan Hines was part of that study?

A. I cannot recall whether or



(ANSWERS BY DR. BUEHLER)

not Jordan Hines was one of the patients for whom we had information available for the child or for the roommates. In other words, to make that comparison we needed to have this normal score for the child and for one or more roommate. There were some children for whom that information was not available, or both. I do not recall whether or not Jordan Hines was one of those included in those comparisons.

Q. Now we know, because we have evidence before the Commission, that Jordan Hines had no anatomical or structural heart defects. I take it that that really is irrelevant to your comments because that would not tell us how much nursing time he required given his condition.

A. The nursing time scores were not based on anatomic defects.

Q. Fine. As well, I would like to take you to page 28, particularly the last full paragraph of your report under "Recommendations", and I am going to paraphrase to save time.

Do I take it from that that what you are indicating is that the regular surveillance program which you recommend is something that could have been implemented at or prior to the epidemic



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1
2 (ANSWERS BY DR. SMITH)

3 period given the then data that the Hospital had.

4 A. The information to construct
5 a curve such as is shown in Figure 3, not exactly
6 like this one but roughly parallelling this one,
7 would be readily available at the Hospital.

8 Q. And I take it the significance
9 of Figure 3 is really by itself to show a dramatic
10 rise in the occurrence of mortality?

11 A. It shows that there was a
12 sharp increase in mortality, yes.

13 Q. My point is this that having
14 observed a sharp rise in the pattern of mortality
15 one could then be put on notice and make other
16 enquiries.

17 A. One would have to try to
18 determine what the source of that rise was.

19 Q. Do I have it correctly that
20 at the given time that I am concerned with, this
21 will be actually somewhat prior to the start of
22 the epidemic in July of 1980, the normal data that
23 the Hospital gathered and had in their files and
24 in their computer banks was sufficient to give
25 them the same information in effect that your
Figure 3 would have given them.



Smith, Buehler,
Wallace, Kusiak,
cr.ex. (Tobias)

(ANSWERS BY DR. SMITH)

A. Except - yes, the answer is yes. However, with one caveat, and that is on a month by month basis one cannot project what is going to happen the next month. So this figure in a sense gives us the perspective of time to be able to really give a - to be able to observe the full profile of this epidemic curve.

For example, if one were to slide a paper across and stop just short, for example of say July, or rather August 1980, one might not have the same information and it would take quite a good deal of information to decide whether in fact an epidemic was about to happen.

Q. When we are dealing though with a nine month period I take it that as we get further into that time period the rise becomes more obvious?

A. Yes.

Q. And that if you look at the figures in September, it becomes a little bit more obvious than it would in August and ergo if you look at it in October a little bit more obvious still.

A. That is correct.



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(ANSWERS BY DR. SMITH)

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Q. So that am I correct in understanding that what would have had to be done given the fact the Hospital had the basic data, was they would have had to basically have asked the question and put the figures together, is that correct? I am talking about mechanically now.

A. Mechanically, yes.

Q. Now, at the time with which we are concerned, do you know, do you have any information whether or not the Hospital had on staff an epidemiologist?

A. (Dr. Wallace) I believe the Hospital does have an epidemiologist, however she is attached to the Infectious Disease Unit and only works in that unit.

Q. Was there an epidemiologist on staff prior to July of 1980 to your knowledge?

A. (Dr. Wallace) I only know of the one attached to the Infectious Disease Unit.

Q. And do you know when she came on staff?

A. (Dr. Wallace) No, I am sorry, I do not know.

Q. Dr. Smith, do you have any



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information?

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A. (Dr. Smith) I believe she

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came on staff in July of 1981.

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Q. Now, at the time of the

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events with which we are concerned, going back to

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the summer, early summer/late spring of 1980, I

8

understand that the Chief of Pediatrics was

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Dr. Carver. Dr. Buehler, do I have it right that

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at one point Dr. Carver was a member of CDC?

(ANSWERS BY DR. BUEHLER)

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A. When I came to Toronto and

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was first introduced to Dr. Carver, Dr. Carver told

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me that he was a former member of the Epidemic

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Intelligence Service of CDC.

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Q. The day before last when you

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were answering, he is almost a doctor at this point,

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Mr. Lamek's questions, I understand that you advised

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Mr. Lamek that Dr. Carver's capacity as far as you

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knew was that he was a former member of the Epidemic

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Intelligence Service, and indeed that was the

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capacity which you first occupied when you went to
the Centres, is that correct?

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A. Yes, that is correct.

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Q. Now, I have examined Exhibit

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184, Mr. Commissioner, which is the CV of Dr. David

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(ANSWERS BY DR. BUEHLER)

H. Carver, and it would appear in fact that he was attached to the U.S. Public Health Service, Epidemic Intelligence Service from 1956 to 1958, and was a member of the Research Division of Infectious Diseases, a branch of the U.S. Public Health Service from 1961 to 1963. Can you tell me, Dr. Buehler, what is a member of the Epidemic Intelligence Service, can you just tell me what those duties are, what background you have to have?

A. First of all I should tell you that my description of the duties of an EIS Officer, or an Epidemic Intelligence Service officer are based on my experience and I cannot comment on how the program may have changed over the years.

Q. All right, that is fair.

A. The Epidemic Intelligence Service officers are most physicians, there are other members of that service who are in other areas of health science or epidemiology. There are a number of different types of assignments that EIS officers may be given. In general the goal of the EIS program is to provide first hand experience in public health practice and epidemiology, and to provide a service for some at the Federal level



(ANSWERS BY DR. BUEHLER)

and for others at the State level.

Q. Would someone engage in such a role be involved with studying the pattern in health of both the public and private sense in the general population?

A. In my capacity as an EIS officer I have been involved in those types of studies.

Q. So that basically it requires, I would take it, over a period of time, or it affords one some experience and knowledge with respect to the study which is what epidemiology is all about.

A. That is a goal of the EIS program.

Q. And such an officer would at least I take it have some rudimentary training and background in understanding for the study of epidemics?

A. Yes, again based on my experience in the program.

MR. TOBIAS: Those are all my questions, Mr. Commissioner, thank you.

THE COMMISSIONER: Yes. Yes, all



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2 right, thank you. Mr. Shanahan, are you ready?

3 MR. SHANAHAN: Mr. Shinehoft is
4 going to go next.

5 THE COMMISSIONER: Yes,
6 Mr. Shinehoft.

7 CROSS-EXAMINATION BY MR. SHINEHOFT:

8 Q. My name is Jack Shinehoft
9 and I represent the parents of Baby Kevin Pacsai.
10 It would appear from the report that you have made
11 with regard to this child, which child is No. 060,
12 and it is page 67 I believe.

13 A. (Dr. Smith) Are you referring
14 to the case summaries?

15 Q. Yes, the case summaries.

16 A. (Dr. Smith) Yes.

17 Q. The case summaries that you
18 prepared with regard to this child. It would
19 appear from my reading that both the clinical
20 pharmacologists and the cardiologists, as well as
21 the pathologists, agree as far as the rating of
22 this child; would you agree with that?

23 A. (Dr. Buehler) Let me just
24 confirm this, this is Child 060?

25 THE COMMISSIONER: Would you agree
that this is what they say?



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MR. SHINEHOFT: Yes.

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DR. BUEHLER: Dr. Nadas has the
timing of death of this child as unexpected and
inconsistent with clinical status. He scored the
pattern of death as consistent with special concern
regarding digoxin intoxication.

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Dr. Kauffman's score was 4 on the
1 to 5 scale.

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MR. SHINEHOFT: Q. Yes, and my
question is would you say that those are shared
views as to the involvement of digoxin with this
particular child?

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THE COMMISSIONER: No, I don't
think they can be asked that. They can be asked
if that is what their experts told them.

MR. SHINEHOFT: All right.

THE COMMISSIONER: That is as far
as that can go, isn't that right? Isn't that what
I understand the rules are?

DR. BUEHLER: Yes.

MR. SHINEHOFT: Would you like
to answer that question?

THE COMMISSIONER: That is what they
say, that is what the report says.

DR. SMITH: That is in fact - those



H11

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2 are the scores according to whatever criteria they
3 used that were given to us for that particular child.

4 MR. SHINEHOFT: Q. Would you say that those
5 two views are somewhat consistent in terms of an
6 opinion?

7 A. (Dr. Buehler) Let us read
8 the criteria that Dr. Kauffman used for Category 4.
9 Turning again to the appendices, the bottom part
10 of the second page, the first appendix:

11 "Rating 4. Patients receiving this
12 rating had the following character-
13 istics:

- 14 1. Clinical course highly suggestive
15 of digoxin toxicity;
16 2. Antemortem serum, postmortem serum,
17 and/or postmortem tissue digoxin
18 concentrations all consistent with
19 digoxin toxicity;
20 3. Cardiac disease which could pre-
21 disposed the patient to digoxin
22 toxicity."

23 Q. Yes. Would you care to
24 comment as to whether you feel that Dr. Kauffman's
25 opinion and Dr. Nadas' opinion are shared in terms
of this child?



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Wallace, Kusiak,
cr.ex. (Shinehoft)

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A. (Dr. Buehler) I think that
would be going beyond what we can say based precisely
on what our consultants told us.



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Q. I see. But you would agree that a rating given by Dr. Kauffman of 4 out of 5 is a fairly high rating and it is one that is only given I believe to one other child.

A. (DR. SMITH) 02064.

Q. So, there were only two children, and correct me if I'm wrong, in your study that received a rating of 4 out of 5 by Dr. Kauffman?

(ANSWERS BY DR. BUEHLER:)

A. Let me just check what Dr. Smith just said. Let me check something very briefly. In the text on page 17 -- actually, let's turn to page 16, the last sentence on that page begins:

"The distribution of scores regarding digoxin intoxication as the cause of death..."

And then if you go on to the top of the next page, score 4, and if you look at the appendix which provides what we have referred to as a line list and look at the digoxin scores that Dr. Kauffman provides there are four patients with a score of 4.

Q. And that is 4 out of how many?



(ANSWERS BY DR. BUEHLER:)

THE COMMISSIONER: 36.

MR. SHINEHOFT: 36, yes.

DR. BUEHLER: Yes. Actually, in these assessments the evaluation for the Woodcock baby was included. So there were actually 37 that Dr. Kauffman did, I think we mentioned that the other day.

THE COMMISSIONER: Yes, all right.

DR. BUEHLER: So, of the 37 that Dr. Kauffman looked at there were 4 that had a score of 4.

Q. All right, thank you. And there was only one I believe, Cook, that had a score of 5.

A. There was one child with a score of 5, yes.

Q. Okay. If I could refer to the conclusions that you have in your report, I believe it is page 28, the second paragraph. I am sorry, it is recommendations, page 28, you state:

"For the future, it is important to recognize that no hospital is immune to the possibility of intentional harm to patients by hospital employees



(ANSWERS BY DR. BUEHLER:)

or others in the hospital. Situations
of this sort have occurred before
and may well occur again."

You have got Footnote 3, which is an article in
the New England Journal of Medicine. I assume that
you have examined that article?

A. Yes.

Q. Have all of you examined that
article?

A. (DR. SMITH) Yes.

A. (DR. WALLACE) Yes.

Q. I believe, Mr. Commissioner,
it was filed as Exhibit No. 152.

THE COMMISSIONER: Yes.

MR. SHINEHOFT: Q. Now, were you
aware of the situations that were referred in the
article before you commenced your study at the
hospital?

(ANSWERS BY DR. BUEHLER:)

A. In preparing to leave
Atlanta to come to Toronto I believe that I had done
some -- that I had found that article and I did bring
that article with me to Toronto.

Q. So you were aware that situations



(ANSWERS BY DR. BUEHLER:)

of not the exact magnitude but situations similar to what may have happened in Toronto have occurred in other jurisdictions, is that correct?

A. Yes. After I learned that I would be coming to Toronto I was made aware of that article and I brought it with me.

Q. And did you perchance examine the references contained in that article; more specifically, references 5, 6 and 7?

A. I would like to have a copy of the article shown to me, please.

Q. All right. I don't know if the article was distributed, Mr. Commissioner. I think I have enough copies of the article that I can give to most of the counsel.

THE COMMISSIONER: Well, I'm sure it was.

MR. SHINEHOFT: I am not sure it was.

THE COMMISSIONER: Very well. Yes, all right.

DR. BUEHLER: Would you please state the question again?

MR. SHINEHOFT: Yes. You say that you



(ANSWERS BY DR. BUEHLER:)

examined that article, Doctor, is that correct?

A. Yes, I read it.

Q. You read it?

A. Yes.

Q. And you will note in the last page there are certain references.

A. Yes.

Q. Did you perchance examine references 5, 6 and 7?

A. No, I did not.

Q. References to certain newspaper articles and certain situations that occurred in other jurisdictions as well, specifically New Jersey and Michigan. Were you aware of those situations, the situation at the Veterans Hospital at Ann Arbor, Michigan?

A. This article describes an investigation at the Veterans Hospital in Ann Arbor.

Q. Yes. So, you are aware of that from the article.

A. Yes. I did not examine references 4, 5 and 6.

Q. That deals with situations that happened in jurisdictions other than in Ann Arbor,



1
2 (ANSWERS BY DR. BUEHLER:)

3 Michigan, a situation in New Jersey. Were you aware
4 of that situation as well?

5 A. I did not review these and I
6 was not aware of these situations.

7 Q. Okay. But before you ever
8 became involved in the situation in Toronto were
9 you aware of anything, any developments that occurred
10 in other jurisdictions similar to what may have
11 happened in Toronto as an epidemiologist?

12 A. I believe you are really getting
13 beyond the range of my testimony.

14 Q. Well, you do make certain
15 recommendations and you do say that this situation
16 has happened before and I was just asking you some
17 questions arising out of your recommendations, really.

18 A. Really, to be precise, I became
19 aware of this article after I learned I was going
20 to be coming to Toronto. I read the article prior
21 to being here and I did not read the references
22 that you mentioned there.

23 Q. Okay.

24 A. In fact, I don't recall if I
25 have read the references in this manuscript.

Q. Well, again, my question is:



(ANSWERS BY DR. BUEHLER:)

As an epidemiologist did you have any previous knowledge or information that would be similar to what has happened or may have happened in Toronto; previous problems with hospitals and with patients and unexpected deaths in hospitals.

A. I don't recall if I had --
you mean in terms of scientific pursuit?

Q. Well, in terms of information that was conveyed to you in your course of training and in your course of study as an epidemiologist, is that a problem that you would have been made aware of or studied, had reference to?

A. My hesitation is coming from some uncertainty as to whether or not I can answer that question and stay within the bounds of the rules that govern my testimony as a witness.

THE COMMISSIONER: Well, I think you can tell about what your experience is, Doctor, I think there is no problem about that, it is your experience.

MR. SHINEHOFT: That is all. That is all I am asking you, Doctor. I am asking you and other members of the Panel what your previous experience is as far as this type of problem is



(ANSWERS BY DR. BUEHLER:)

concerned.

THE COMMISSIONER: If you had a problem in any way relating to this in your experience before.

DR. BUEHLER: As part of my training as an epidemiologist, I had not had familiarity with a problem of this type before.

THE COMMISSIONER: Where is this leading, Mr. Shinehoft?

MR. SHINEHOFT: Well, there is a recommendation made and there are certain articles referred to, and I have read those articles, Mr. Commissioner, and these questions arise out of those articles very simply.

THE COMMISSIONER: Well, what is it, are you complaining about the recommendations?

MR. SHINEHOFT: No, I am not complaining about anything at all. I just want to know the information that the members of the panel have and to question them about that information.

THE COMMISSIONER: Well, have you had a sufficient answer now?

MR. SHINEHOFT: Well, perhaps other members of the panel could answer that question



Smith, Buehler,
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(ANSWERS BY DR. BUEHLER:)

as well as to their previous knowledge of this
type of situation. Dr. Wallace?

A. (DR. WALLACE) I have been
involved in many infectious disease and outbreak
situations. The only situation that may be similar
to this one was again an outbreak of what initially
was an unexplained illness in the intermediate care
intensive unit at Sick Children's Hospital in
January of 1982.

Q. That is the epinephrine, vitamin
E problem?

A. (DR. WALLACE) That is correct,
yes.

Q. Dr. Smith, are you aware of any
similar situations in your experience or in your
educational background?

THE COMMISSIONER: I am getting a
little worried about this, Mr. Shinehoft.

MR. SHINEHOFT: This is my last
question.

THE COMMISSIONER: I just want to
say it will take several ten ton trucks to make me
draw a conclusion because it happened somewhere else,
rather than it happening here, that's all.



10 1
2 (ANSWERS BY DR. BUEHLER:)

3 DR. SMITH: I received the New
4 England Journal of Medicine and had read that
5 article before but it had not, this type of
6 investigation had not been part of my training and
7 I have been involved in outbreak investigations
8 outside of hospitals but not in hospitals.

9 MR. SHINEHOFT: Thank you very much,
10 those are my questions.

11 THE COMMISSIONER: Thank you. Mr.
12 Shanahan?

13 MR. TOBIAS: Mr. Commissioner, I
14 apologize to you, sir, I don't mean to disrupt these
15 proceedings but I did have one very short area.

16 THE COMMISSIONER: All right.

17 MR. TOBIAS: I will be honest with you,
18 it was on the opposite flip side of my notes and
19 that's why I missed it, if I could have your indulgence
20 for a few minutes.

21 THE COMMISSIONER: No harm done.

22 (FURTHER CROSS-EXAMINATION BY MR. TOBIAS:)

23 Q. The point that I would like
24 to bring out is simply this. I understand that in
25 beginning your exercise it was the hospital itself
that provided you with draft terms of reference?



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A. (MR. SMITH) That is correct,

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yes.

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Q. I also understand that the terms

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of reference as they ultimately appear in

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your report are almost identical to the terms

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of reference prepared by the hospital. Was there

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any avenue, any suggestion made to you by the hospital,

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any area of concern that they raised or anything that

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they asked you to do that you did not pursue?

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A. (DR. SMITH) We pursued every-

thing that they requested.

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Q. Okay, fine. Now, with respect

to your own thought process ---

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A. (DR. BUEHLER) May I just add as

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best as I can recall; to the best of our recollec-

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tion, to the best of what I can remember. Are you

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asking specifically about the terms of reference?

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Q. I am really going beyond that.

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What I am asking you is this. Was there any major

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undertaking or, I won't use the term major, it is

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slightly pejorative, was there any significant

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undertaking which the hospital asked you to look at

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which you refused to take a look at that you can

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A. (DR. BUEHLER) In terms of

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12 1
2 (ANSWERS BY DR. BUEHLER:)

3 specific hypotheses?

4 Q. And in terms of specific
5 methodology.

6 A. Okay, the hospital did not
7 recommend to us specific methodologies. The hospital
8 did give us a set of terms of reference.

9 Q. Were there any avenues that
10 you can recall their asking you to pursue that you
11 refused to pursue?

12 A. (DR. SMITH) I do not recall
13 not pursuing anything that they were interested in.

14 Q. All right. And is it not fair
15 to say that if there was such a substantial or
16 significant avenue you would recall that?

17 A. (DR. SMITH) Yes.

18 Q. All right, fine. Now, with
19 respect to your own thought processes and your own
20 analysis, and you have obviously devoted a major
21 portion of your life really to the preparation of
22 this report, today, if you had to do it all over
23 again, are there any major changes that you would
24 make to your methodology?

25 A. (DR. BUEHLER) Let me step
back. We are here to testify on the findings that



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(ANSWERS BY DR. BUEHLER:)

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we made and to avenues of investigation that we

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took followed in a step-wise manner more or less,

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as we have already mentioned, using as best we

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could the types of information that were available

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to us. That is as far as I care to go in answering

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that question.

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(ANSWERS BY DR. SMITH)

Q. All right. The question really is this, is it not: I asked you about avenues that the Hospital suggested that you pursue and you told me that as far as you recall whatever avenues they suggested you did pursue.

Are there any avenues today, looking back on it all, any avenues that you did not pursue that you thought were important?

A. I think in answer to that I can say we were not in any way limited by the terms of reference if we felt that there were other avenues which would add information to those terms of reference. That is that we would have pursued them.

Q. All right. Are you satisfied, though, with respect to the preparation of this report, the avenues that appeared to you to be most significant and the methodology that appeared to you to be most significant was pursued?

A. Taking into consideration the limits of the data that were available, we pursued it as far as we could.

MR. TOBIAS: All right. Fine. Those are all my questions. Thank you.



J2 1
2 THE COMMISSIONER: Thank you.

3 Mr. Shanahan.

4 If you don't have any regrets in
5 life you are almost superhuman I would say. I
6 certainly have.

7 Yes, Mr. Shanahan.

8 CROSS-EXAMINATION BY MR. SHANAHAN:

9 Q. Good morning. My name is
10 Shanahan and I act on behalf of the parents of two
11 of the children, Lombardo and Dawson.

12 One of the things here, just if I
13 might, on the general sort of approach you had to
14 this time period, it struck me reading the evidence
15 yesterday that you gave to Mr. Lamek that you were
16 aware of various theories; you were working in
17 close proximity to the police and a lot of other
18 people had input too, sort of if you like, pet
19 theories or feelings on what might have occurred
20 there and you were aware of them. Am I clear on
21 that? Is that right?

22 (ANSWERS BY DR. SMITH)

23 A. We were working in physically
24 close proximity to the police inasmuch as they were
25 a few rooms down the hallway. I would not say that
we were working close enough to be having a joint



Smith, Buehler
Wallace, Kusiak
cr.ex. (Shanahan)

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(ANSWERS BY DR. SMITH)

investigation, no.

Q. But somewhere, whether from your own previous experience or whatever, what you do is you initially approach it, as appears from the report, and you look at, and you discount, if you like, various innocent - for the use of a better word - explanations for what occurred during this time period.

On page 19 the conclusion seems to be that you say that the following variables -- you don't observe any association between death and those variables, and there are many of them. That is, the procedures that they might have had, the duration of their stay and whether they had surgery. You eliminate at the outset it appears to me the innocent or innocuous explanations for what clearly was an epidemic period.

Am I right there?

A. (Dr. Buehler) Are you reading from page 19? Are you looking at the death roommate study?

Q. Well, I am more interested there -- it seems to me what you did is you considered here not only the death roommate study, but in your



J4

(ANSWERS BY DR. SMITH)

report in general as you approached, once you had assessed there was an epidemic period that you looked at possible neutral or innocent explanations, increase in patients, more severe, younger, you went through the very obvious, and as I say again neutral or innocent explanations that might very quickly have accounted for what appeared to be an epidemic. Am I right there?

A. Well, rather than use the word "neutral", we looked at all the possible situations which might have an effect on mortality.

Q. All right.

A. Variables that is.

Q. It seems to me that those variables were ones that -- variables, if you call them variables -- those considerations were obvious ones that might strike any layman let alone an epidemiologist right off. Were these younger kiddies? Were they sicker kiddies?

And it struck me picking up on something that Dr. Wallace got into yesterday that in the final analysis or at least your first approach is not to zero in on staff and the presence of particular nurses or doctors initially. As I



Smith, Buehler
Wallace, Kusiak
cr.ex. (Shanahan)

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(ANSWERS BY DR. SMITH)

take it your chronology initially was to see if there was an immediate innocent or neutral explanation for the occurrence?

A. That is what we stated, yes.

A. (Dr. Buehler) Let me amplify that slightly.

Q. Yes.

(ANSWERS BY DR. BUEHLER)

A. We looked at a variety of conditions that reflect patient care, et cetera, and as has been emphasized previously the indicators that we looked at, none of them showed a change coincident -- a marked change coincident with the onset of what we defined as the epidemic period except for the question of ICU occupancy where we did observe that during that nine-month period there was a greater number of months where the occupancy exceeded desired levels.

Q. All right.

A. Then in your question you sort of combined two different parts of our study.

We then attempted or actually very early in the process we attempted to collect information that might allow us to calculate age or



J6

(ANSWERS BY DR. BUEHLER)

severity adjusted mortality rates. In other words, information that would allow us to take into account changes in age characteristics or severity characteristics of the patient population. That type of information was not available to adjust mortality rate calculations.

However, we did attempt to look at a sample of patients who began hospitalization on the cardiology ward before, during and after the epidemic period, and as stated previously there is some concern about the tabulation of that data as is presented in our report.

Q. All right. The thrust of my question is that you immediately get into various associations and factors and that you quite quickly in the report deal with them on a statistical basis and you come to the conclusion that, yes, we have an epidemic and until we get to the position where we are talking about the presence or absence of certain nurses, until we get to there, you methodically -- you just eliminate them. They don't appear to be significant to you.

Am I right there so far?

A. We looked at a range of things



Smith, Buehler
Wallace, Kusiak
cr.ex. (Shanahan)

J7

(ANSWERS BY DR. BUEHLER)

and had negative findings and didn't pursue those further.

Q. All right. And then when you get to the human level, and picking up on what Dr. Wallace said yesterday, perhaps from a medical point of view, the least palatable suggestion here becomes, would you agree, as we look back on the whole report, it becomes the most significant finding that you make in that report, and that is that when you eliminate all the other factors about age and severity, what we get right down to then is the only common factor that you finally find running through this epidemic period other than the epidemic period itself, deaths, is the presence or absence of this Nurse 401?

A. (Dr. Smith) Well, it was clearly stated that that is the strongest association that is found.

Q. Yes.

A. (Dr. Smith) I think that speaks for itself.

Q. Now then as well as that here, the association that you came to or the finding that you came ^{to} with respect to there being an epidemic per se,



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(ANSWERS BY DR. BUEHLER)

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in fairness as I gathered from reading the report that really it was a finding you were able to make very quickly, and on factors and data that was all contained within the Hospital -- indeed at the Hospital's fingertips and at your fingertips as you went through your review.

A. As we have said we were able to use available information within a very short time after arriving and generated a figure that resembled Figure 3 of the report.

Q. My point is that in terms of that for other areas you had to retain outside consultants, and for other areas you had to retire perhaps back to Atlanta and sit down with rather complex configurations and data and numbers, but with respect to the finding per se that there was an epidemic period and that there had been a dramatic and statistically significant increase in deaths, those facts in support of that finding were all right there within The Hospital for Sick Children? Am I right there? That is the number of patients, the number of deaths?

A. (Dr. Smith) Yes, that is correct. There are no numbers there that were



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(ANSWERS BY DR. BUEHLER)

created. They were available at the Hospital.

Q. Yes. They were at your fingertips; they were made available and indeed by implication they were therefore at the fingertips of the Hospital itself?

A. It might be important to provide one bit of background information and it is something that your question brings to mind, and that is when we started our investigation the Hospital knew that we were coming and did everything they could to very quickly provide us with some information.

Now we don't know if the rapidity of their compliance with our request might have been affected by the fact that they had already gathered that information either in anticipation of our arriving at the Hospital or for investigations that the Hospital itself had undertaken.

But you are correct in stating that using information the Hospital provided we very shortly after arriving established that there was a sharp increase in mortality rates.

Q. Yes. Well, you added the word "shortly", and that was the last question on



1
J10 2 (ANSWERS BY DR. BUEHLER)

3 this area. Not only was that data available right
4 within the Hospital itself, and I put to you easily
5 available, but secondly once you had that data the
6 work you had to do with it, the mathematical
7 configurations you had to do were something that
8 could be done very quickly, and you very quickly
9 realized you had a statistically significant
amount of deaths, an epidemic?

10 A. We very shortly after arriving
11 generated a figure that resembled Figure 3 using
12 the data that was there at the time.

13 I don't recall whether or not we
14 immediately did statistical tests of relative
15 risk and confidence limits.

16 Q. No, no.

17 A. But examination of Figure 3
or the ancestor of Figure 3 if you will.--

18 Q. Yes.

19 A. -- the precursor demonstrated
20 a sharp increase in mortality.

21 Q. All right. And that led
22 then to your conclusion on page 28. One of the
23 conclusions you made was that if there was a
24 regular surveillance of mortality patterns -- so that
25



J11

(ANSWERS BY DR. BUEHLER)

I don't misstate here I am going to read it. It is
the last paragraph on page 28.

"Regular surveillance of mortality
patterns in the Hospital could have
identified the epidemic problem in
the early fall of 1980 and thus have
led to earlier corrective action. A
clear excess of deaths associated
with the nighttime occurrence on
Wards 4A/B, and perhaps related to
a particular team of nurses, could
have been detected by that time..."

And I take it "by that time" you are referring to
the fall of 1980.

"...had a system been in place which
regularly scanned death frequencies
by ward and date of occurrence. The
Hospital already collects on a
monthly basis the data needed for
such surveillance: a monthly list
of deaths in the Hospital showing
date and place (ward) of occurrence
together with monthly ward-occupancy
figures."



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(ANSWERS BY DR. BUEHLER)

And you say in the last sentence:

"Together these two pieces of
data could be simply scanned each
month for ward-specific mortality
rates..."

So I gather from that the data was there, that the
process to find out there were increasing mortalities
was a simple process. Am I right there?

A. You read the report correctly.

I think that to look at mortality
rates they would need to actually calculate the
rate based on deaths and mortality — based on deaths
and occupancy or patient days, and it would be
possible to visually monitor a pattern of deaths.

Q. All right. Now moving on --

THE COMMISSIONER: Mr. Shanahan,
unless you are in trouble this afternoon I would
like to break off now.

MR. SHANAHAN: No, no, I am fine.

THE COMMISSIONER: You are not in
trouble for once?

MR. SHANAHAN: No. No, I am in
great shape.

THE COMMISSIONER: Then we will rise
until 2:30.

--- luncheon recess.



Smith, Buehler,
Wallace, Kuziak
cr. ex. (Shanahan)

AA
DM/PS

1 ---Upon resuming at 2:35 p.m.

2 (ANSWERS BY DR. BUEHLER:)

3 THE COMMISSIONER: Yes, Mr. Shanahan.

4 Q. I believe I left off at the
5 last point before lunch with respect to the data
6 aspects there. Would you agree with me, finally
7 dealing with that issue, that the same time effort,
8 and really more to the point expertise that was
9 put into review, the McMaster review, I will call
10 it, of your report, were put into analyzing
11 the data that was already in the hospital. It would
12 have been known in the fall of 1980 that indeed
13 they were dealing with an epidemic and that the
14 characteristics of that epidemic which you have
15 remarked upon, that is that it was located in one
16 ward predominantly, it was predominantly associated
17 with one nursing team, and that predominantly the
18 deaths were occurring between the hours of midnight
19 and 6 a.m. would have been readily apparent.

18 A. We know roughly how many months
19 it took the McMaster group to prepare their report
20 but we don't know how much time they spent working
21 on it, and I can't answer that question.

21 Q. The babies that I act for are
22 Lombardo and Dawson. With respect to Baby Dawson,
23 Baby Dawson is in category A, as is Baby Lombardo.
24
25



(ANSWERS BY DR. BUEHLER:)

A. Yes.

Q. With respect to Baby Dawson, I just think to sort of summarize here, I think Dr. Nadas indicates in his notes, in his work notes, that he felt she should have been in ICU at the time of her death. I think in the chart that is at the end of your study the comment is made, or she is listed under the category:

"That a higher level of care would have been desired."

Is that a fair enough summation of Baby Dawson's position there?

A. I think it is important to emphasize what that means. That was the relative scale that Dr. Nadas used and he emphasized to us, and I believe it is stated clearly in the report, that that judgment is not intended to reflect upon the judgment of the physicians at the Hospital for Sick Children.

Q. That was using, applying the standards, he had just simply, I take it, a number status on this baby and he was applying the status that he would have applied, or the criteria that he would have applied at his hospital, he didn't



(ANSWERS BY DR. BUEHLER:)

mean it as a criticism of Sick Children's at all.

A. That is my understanding.

Q. One final thing with respect to Baby Dawson; on page 16 under "Pathologist's Consultation", you go through the autopsies that were performed and you give various numbers and ratios. There is one thing that concerned me, and this is about line 6, the sentence that starts:

"For three deaths..."

And it gives the case numbers:

"...the consultant pathologist expressed concern that available autopsy findings did not fully account for the patient's demise."

It gives the numbers, and those numbers bear out to be Woodcock, Hines and Pacsai.

Now, as I understood it from your evidence Dr. Nadas would have, and all of you had at your disposal, I may be wrong and if so you can correct me, if this assumption is wrong then it will explain it; I thought you had at your disposal all of the records and the charts that were available, and part of the Dawson record was a Coroner's Investigation, and in fact an autopsy prepared by a



(ANSWERS BY DR. BUEHLER:)

pathologist at Sick Childrens a Dr. Kutz.

First of all, before we go any further would Dr. Nadas have had that, do you know, at his disposal?

A. This section of the report, "Pathologist's Consultation", deals with the evaluations done by Dr. deSa.

Q. Dr. deSa.

A. And Dr. deSa reviewed the autopsy records that were available and those were his impressions.

Q. Dr. deSa. What I am saying then, the same question then, Dr. deSa presumably would have dealt with no other pathology report other than the one prepared by the coroner, or by Sick Children's, Dr. Kutz at the request of the coroner and that are contained in the Dawson medical records, that would be what he reviewed.

A. Could I ask a question? May I have Dr. deSa's report?

THE COMMISSIONER: Yes, it is an exhibit.

THE WITNESS: It is an exhibit?

THE COMMISSIONER: Yes. Would you like to see it?



(ANSWERS BY DR. BUEHLER:)

DR. BUEHLER: Yes, please.

THE COMMISSIONER: Does anybody know
the number of that?

MR. LABOW: It is Exhibit 283.

THE COMMISSIONER: Exhibit 283.

DR. BUEHLER: Can you tell me quickly
what the number for your client is?

Q. For Dawson?

A. Yes.

Q. 02004.

A. Thank you. It has been some
time since I read Dr. deSa's report since it was
separate from ours. I believe that Dr. deSa pro-
vided him with the background material, the criteria
that he used to make his assessment.

Q. Yes. One thing I am briefly
concerned with here is we have seen this autopsy
report and we have gone through it and I am not going
to go through it now with you, I presume you have
had it at your disposal. That autopsy report
clearly goes through the surgery that was
performed on this child, indicates that surgery was
successful and was properly done and indicates



(ANSWERS BY DR. BUEHLER:)

they don't find any immediate cause or explanation for the death. That really was clear. The coroner had been called in and that report has still left all of us in terms of finding an anatomical cause of death, it has left us with no cause given. I am concerned here why then Dr. deSa, if you wish to pass the question on to him, would consider that only three deaths did not fully account for the patient's demise.

A. I cannot speak for Dr. deSa's judgment.

Q. Let us move on to Lombardo. Lombardo was a category A death. At page 13 you talk about, at the top, after the 3, 4 number you say:

"Lastly, the consultant attempted to suggest possible routes and times of administration of overdoses in the four cases where sufficient digoxin data to support such estimates were available."

All right, there were four cases there where Dr. Kauffman could take you back and give you an estimated time where the drugs were given and Lombardo was one



(ANSWERS BY DR. BUEHLER:)

of those four, is that correct?

A. That is correct, yes.

Q. On page 16, on the bottom, the last two sentences:

"In most patients who had been receiving prescribed doses of digoxin, it was not possible to distinguish between therapeutic and toxic digoxin levels in post mortem tissue specimens. Four patients had digoxin present in post mortem specimens without digoxin having been prescribed."

Now, again Lombardo was one of those four, is that correct?

A. That is correct.

Q. So Lombardo is a category A death, it is a death in which you can get fairly accurate time given to you when the digoxin might have been given prior to death, by Dr. Kauffman. As well that is one of four children where we find digoxin in tissue and it hasn't been prescribed.

A. I think Dr. Kauffman, both in the information that he provided with us, and I cannot vouch for the information he may have provided



(ANSWERS BY DR. BUEHLER:)

earlier, I think Dr. Kauffman felt that those times of administration were approximate.

Q. Yes, he did indeed, no question.

A. You had used the words, "fairly accurate".

Q. All right, approximate times, but he has got four he gave as approximate times, and Lombardo is one of those as well, in addition to being a category A.

A. That is correct.

Q. And as well as that there are four children in which you find in tissue a trace of digoxin where there was not any digoxin prescribed to those children, and Lombardo was one of those four as well.

A. That is correct.

Q. Now, you come to Table 12 on page 47 of the report. You point out here with respect to the children, Lombardo, Inwood, Miller and Cook, one nurse, Nurse Trayner is on duty for all four of the deaths as I read that, am I right?

A. Right. Yes, what we are saying there is given the assessments of time that Dr. Kauffman gave us for those four deaths, there



(ANSWERS BY DR. BUEHLER:)

was only one nurse, according to our nursing calendar, who was on duty at those times in all four.

Q. When it would be estimated by Dr. Kauffman that the dose was administered?

A. That is correct.

Q. There are five others at the time, within that time period with respect to possible administration to Lombardo, Nurses 103, 104, 502, 504, and 605, and as I look at your total down at the bottom that is the only one of the four, the four that Dr. Kauffman can give us an estimate on that those nurses are on for, that is the child Lombardo, am I right there?

A. I am sorry, are you asking me about Nurses 103, 104?

Q. 104, 105, 502, 504 and 605. It seems pretty obvious that is the only child that they are on for is Lombardo.

A. That is correct.

Q. And apart from just this, as you move to your other tables, those nurses as well you will agree, I don't believe, are on at all, or at least let us say they are not statistically



1
2 (ANSWERS BY DR. BUEHLER:)

3 significant at all in terms of relative associa-
4 tion to deaths over this whole time period.

5 A. I would have to take a moment
6 to check that out.

7 Q. Would you do that, please, and I see
8 in another part of Table 11 here ranging from
9 44 to 46 it seems to be perhaps 504.

10 A. I am looking at the last page
11 of Table 11.

12 Q. 504 is the only one who seems
13 to come into view at all, and I would submit to you
14 she is statistically, she is not significant in
15 terms of the 36 deaths, or rate of association.

16 A. The relative risk for Nurse
17 504 is 1.1 with a confidence limit of 0.4 to
18 2.2. As we have mentioned earlier, that is not
19 a statistically significant association. In fact
20 as we have said earlier, a relative risk of 1
21 is indication of no association.

22 Q. And the other four of the five
23 are not even mentioned at all, those other four
24 nurses.

25 A. They do not appear on the last
page of the Table 11.



(ANSWERS BY DR. BUEHLER:)

Q. Finally, then where everyone else has tracked and that is the last two pages, pages 27 and 28 of your report; on page 27, about ten or 11 lines from the bottom there, you put in a sentence there:

"Although these observations suggest that some infants died as a result of intentional administration of digoxin overdoses, it is not possible from this investigation alone to make this determination conclusively."

I take it by that when you say, "this determination" you are talking about whether they died as a result of an intentional administration, that is the determination that you don't think you can determine conclusively, am I right there?



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(ANSWERS BY DR. BUEHLER)

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A. Yes, an epidemiologic study
could not make such a determination.

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Q. All right. But then on
page 28 under your Recommendations, skipping the
first sentence for a moment you say "If it is
decided,..." and then you say "...as the evidence
suggests, that the increased occurrence of deaths
from July 1980 through March 1981 resulted from
purposeful IV overdoses of digoxin on Wards 4A/B,
then it remains to be decided whether there is
sufficient evidence to identify the perpetrator.
This matter rests with the law enforcement authorities."

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So, in that sentence here first of
all you are saying that the evidence does suggest
that there has been purposeful overdoses. You don't
seem to have any doubt as you draft that sentence
about purposeful or deliberate or on one side and
intention or a lack of it on the other side, you
seem to say there the evidence suggests it is
purposeful and that the only question that really
remains is whether there is evidence to give us
identity. Do I not read that right?

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A. I think it is clear that what
we have said, our report does not attempt to



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(ANSWERS BY DR. BUEHLER)

determine conclusively whether or not intentional acts were committed. That is clearly beyond the range of our investigation.

Q. Well, that's what you say on page 27. There is no question that sentence says you can't make this determination, that's the one of intention on this report alone.

A. Yes.

Q. But when you come to this sentence here you say the evidence suggests that they were caused, the increased occurrence was caused by purposeful overdoses and the only thing remains is whether there is sufficient evidence to identify the perpetrator.

A. If others make that decision, clearly, that is not our decision to make and I would be very cautious to emphasize that word "suggest".

Q. Well, the decision isn't yours to make whether there is sufficient evidence to identify the perpetrator but you do seem to suggest there that the matter of intent and deliberateness seems to be, the evidence seems to suggest that it was purposeful overdoses. The only thing you leave



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(ANSWERS BY DR. BUEHLER)

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open to the law enforcement people is to find out
who in fact the perpetrator might be.

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A. That is not the intent of

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that paragraph.

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Q. It is not the intent, but you

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would agree that the wording is there to read it

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just as I have put it to you?

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A. That is not the way I read

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that sentence, nor is it the way we intended it

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to be read.

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Q. All right. If somebody then

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were trying to find out, except if you read my way

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for a moment for the sake of argument here, and

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were then trying to find out the perpetrator,

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first of all, sir, you will agree that the first

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sentence "The epidemic clearly ended in March of

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1981", all right, and you know and we know what

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happened in March of 1981, digoxin was put under

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lock and key and that nursing team was disbanded.

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You know that, don't you?

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A. We are aware of that.

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Q. All right.

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A. We mentioned in the introduction
to our report that the routines for prescribing



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(ANSWERS BY DR. BUEHLER)

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digoxin were changed.

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Q. All right, and that the nursing team was disbanded. You know that? You didn't get into that and that is why I am putting it to you.

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A. We are aware of a nurse being arrested and charges being laid against her.

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Q. I really don't want to get into it that far.

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A. And we were aware of the team being temporarily disbanded.

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Q. All right. The team was disbanded, quite apart from...

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A. Yes.

Q. All right. And you will agree then that first of all in terms of people deciding about sufficient evidence, that in and of itself, your feeling that it clearly as you say ended, statistically you are satisfied that it ended in March of '81 and that another factor that the team was disbanded and that the drug itself went under lock and key, that is one factor that would be noteworthy. You will agree there?

A. It is our understanding that



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(ANSWERS BY DR. BUEHLER)

after March, 1981, at least through the time that we were at the Hospital and I believe up to the time that our report was submitted, there were no further deaths where concern was raised about similar high levels of digoxin that were observed in some of the other cases.

Q. Was that correct?

A. Was that correct?

A. (Dr. Smith) I believe that there was one.

THE COMMISSIONER: April, 1983.

DR. SMITH: In April last year.

DR. BUEHLER: That would have been after our report was submitted.

DR. SMITH: Yes.

MR. SHANAHAN: Q. All right. But your sentence that it clearly ended in March of '81, you are satisfied that it ended but you do know two other external facts I had given to you that I think are significant and I think you will have to agree are significant and that is digoxin is put under lock and key and that that nursing team was disbanded. You will agree that is a significant factor.



(ANSWERS BY DR. BUEHLER)

A. I agree that those events are associated with the end of the epidemic.

Q. All right. Second of all here you will agree here in terms of sufficient evidence and other people assessing whether there is sufficient evidence, you will agree that your study itself both in all the things that it eliminates, all those factors about sex and age, the severity of their illness, over-crowding, the factors it eliminates and then the factors of association that it brings to view and highlights, you will agree, that is significant as well?

A. The word "significant" is an awkward one to use because it means one thing to a statistician and another...

Q. Well, you will agree then that your report insofar as the study done on Table, I think it is Table 11 that gives you the relative risks, am I right there, is that the table?

A. Yes.

Q. Table 11 with respect to the relative risks and pointing out the presence of Nurse Trayner with respect to a predominant number of these deaths, you will agree here that



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(ANSWERS BY DR. BUEHLER)

again bearing in mind that paragraph on page 28 about whether there is sufficient evidence to identify the perpetrator, that that table in itself purely on a matter of association is another piece of evidence that one can look at with respect to identifying the perpetrator?

A. One of the concerns that we have had all along is that the epidemiologic findings not be misused and I think it is extremely important to remember that we are not criminal investigators, that we are dealing with observed associations based on the information at hand. We did observe a statistically significant association between Nurse 401 and the occurrence of deaths during that nine-month period.

Q. All right, that is all I wanted to get at.

Finally then at the top of page 28, and I bear in mind here, and I am not trying to slide something by you here, it commences on the bottom of page 27 and it commences on the hypothetical, if the epidemic was a result of intentional acts. All right, you say there are several noteworthy patterns in the series of crimes committed. I take



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(ANSWERS BY DR. BUEHLER)

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it the rest of the paragraph is premised on that
4 hypothesis.

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A. Yes.

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Q. But to coin a phrase you

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used yesterday you then seem to give a profile of
the person, the characteristics or training or
8 skill of the person that might in fact be the
9 perpetrator and you say, starting at line 2:

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"Because the epidemic went
11 unrecognized for almost 9 months,
12 suggesting that the perpetrator had
13 enough clinical knowledge to choose
14 victims whose deaths would not
15 initially be considered suspicious."

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There is one factor. You say:

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"The perpetrator would also need to
18 have been a person who had unlimited
19 access to patients over a 9 month
20 period."

21

There is another. Finally:

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"Neither the presence of such a
23 person in a patient room if observed
24 nor the act of his/her handling an
25 IV line during night-time hours



BB9

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(ANSWERS BY DR. BUEHLER)

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"would arouse suspicion."

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Finally then in terms of that profile you will agree that all members of that nursing team, and specifically Nurse Trayner, meets those three characteristics of the profile that you put there.

A. You have taken one step more than we chose to take in that paragraph.

Q. Okay.

A. That paragraph is clearly a matter of speculation, as I stated yesterday.

Q. Well, it is speculative about the intention part but it isn't speculative about the characteristics of the profile itself.

A. Every word in that paragraph is prefaced by the phrase "If the epidemic was the result of intentional acts". I think it is extremely important that these findings not be over-stated.

THE COMMISSIONER: I think you mean be under-stated.

DR. BUEHLER: Pardon? Or be under-stated, you are correct.

MR. SHANAHAN: Q. I am suggesting



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(ANSWERS BY DR. BUEHLER)

to you whether they were deliberate or intentional that the profile of the person giving it would still be the same, more so if intentional mind you, but I am saying that your qualification there at the beginning of that paragraph doesn't change the three characteristics of the perpetrator that you set out there, first of all, and then my second question is going to be, doesn't that portrayal there fit both the nursing team and specifically Nurse Trayner.

A. If the initial phrase of that paragraph read "If the epidemic was the result of accidental acts" then I believe the sentence that begins with the word "The cause of..." suggesting that the perpetrator had enough clinical knowledge, et cetera, that sentence would not be particularly relevant.

Q. All right, I will leave it at that then.

One final one then. To your knowledge, is there any factor about population or a disease or a condition which would cause deaths that you know to occur predominantly between those hours, 12:00 and 6:00, and only when a certain nurse, Nurse



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(ANSWERS BY DR. BUEHLER)

Trayner was on duty? Do you know of any other conditions or factors which would cause that coincidence of features?

A. We did not find a disease pattern that could be described by those events, you are correct.

Q. All right. That would have those coincidence of factors about time and nursing team and specifically one nurse?

A. Our investigation could not identify a disease that had those coincidence factors.

MR. SHANAHAN: All right, thank you very much.

THE COMMISSIONER: Thank you, Mr. Shanahan. Mr. Strathy?

MR. STRATHY: Mr. Commissioner, do you mind if I address my questions from this location?

THE COMMISSIONER: No, that is fine.

CROSS-EXAMINATION BY MR. STRATHY:

Q. Ladies and gentlemen, my name is Strathy, I represent Nurse Trayner whom you may know as Nurse 401.



Smith, Buehler,
Wallace, Kusiak
cr.ex. (Strathy)

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Now, as you might expect, my client is quite interested in the things you have to say. She has read your report, she has some questions about your report, as I do, and I would like to address some questions to you about your report and I hope I won't repeat things that have already been asked of you; if I do, try and bear with me.

As I understand it, and perhaps I will start by addressing my questions to Dr. Buehler if I may, you basically started your enquiry in July through September of 1982, am I right on that?
(ANSWERS BY DR. BUEHLER)

A. We began in September of 1982.

Q. So, you were retained in approximately July but the investigation itself started in about September?

A. The initial communication which eventually lead to our involvement I believe was in July.

A. (Dr. Smith) July 29th I believe, July 30th.



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(ANSWERS BY DR. BUEHLER)

Q. But the actual work itself
didn't start until the fall?

A. That is correct.

Q. And at the time you commenced
your work would you agree with me it was well known
certainly to all of you, and if any one of you
disagree, please let me know, that the question of
the association of these deaths with the nursing
staff at the Hospital was something well known; is
that fair?

A. We were well aware of the
fact that a nurse had been arrested and charges laid.

Q. And did you know that a nurse
indeed who was a member of this particular team had
been charged with four of these deaths?

A. Yes, we were aware of that.

Q. And were you also aware of
the fact that my client, Mrs. Trayner, was the team
leader on that particular team?

A. We learned that.

Q. Learned it I assume fairly
soon after becoming involved in the matter; is that
fair?

A. At some time. I don't recall



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(ANSWERS BY DR. BUEHLER)

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exactly when we learned that.

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Q. Would it have been at a

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relatively early stage?

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A. I think so.

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Q. Certainly when you took up

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your investigation this whole question of association

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with nurses was something that was pretty hard to

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A. As we stated, we at the

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outset did not necessarily plan to look at that.

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That was a decision that was made later on in the

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investigation.

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Q. Well, just to go back to

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my question. The fact of the association was

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presumably something pretty hard -- you couldn't

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A. That was --

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Q. It received a good deal of

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publicity?

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A. Yes, that is obvious, yes.

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There was certainly a great deal of publicity about

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that.

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Q. And certainly when you went

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into the investigation I would suggest that one of

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(ANSWERS BY DR. BUEHLER)

the things you had in mind to look at, obviously,
was going to be association with personnel at the
Hospital?

A. Yes.

Q. And more specifically, I
suppose, association with nurses in the Hospital?

A. That is not precise because
we felt it was important to look at those Hospital
personnel who had prolonged times on the ward on a
24-hour basis; namely, physicians and nurses. We
felt it was extremely important to, as best we
could, look at evidence relating both to physicians
and nurses.

Q. So when you went into this
study then it was extremely important to you not just
to focus on nurses?

A. Yes.

Q. You wanted to look at the
possibility that other personnel in the Hospital
may have had an opportunity, let's call it that?
Is that fair? Or association, let's call it --

A. Association is a better word.

Q. Is that the word you would
use?

A. Yes.



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(ANSWERS BY DR. BUEHLER)

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Q. So that the question of association then from your point of view as epidemiologists going into this study was not to be confined to nurses. It should have been a broad spectrum of Hospital personnel presumably?

A. As it turned out we focused mainly on doctors and nurses, but that focus was made after other results and information were available.

Q. That was a decision, though, which was dictated by the practicalities of the situation; is that fair?

A. There were practicalities of the situation which dictated the amount of detail with which we could examine the presence or absence of physicians and nurses; however, there were other reasons why we focused on those two groups.

Q. Well, the practicalities that I was referring to was the practicality of availability of data. Is that fair?

A. Yes.

Q. All right.

Looking at it as scientists and as



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(ANSWERS BY DR. BUEHLER)

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epidemiologists I understand you are scientists and

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going in in the first instance ideally what you

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would like to have would be data about all the

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Hospital personnel who might have had an association
with these deaths; is that fair?

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A. Ideally in initially approach-
ing the situation, yes.

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Q. All right. So your evidence is
as I understand it then, starting off you were not
simply focusing on nurses; you were focusing on
anybody who might have had an association at these
times and was linked to the Hospital in some way,
and as your investigation progressed, for reasons
primarily of practicality as I understand it, you
focused on nurses and doctors?

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A. We focused on nurses and
doctors, but that was not primarily a reason of
practicality. If, for example, we had found that
there was an outbreak that had occurred between
noon and four in the afternoon we would have
broadened our scope.

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Q. All right. But even within
those frameworks, the framework of the deaths
occurring at night, there were other personnel in



Smith, Buehler
Wallace, Kusiak
cr.ex. (Strathy)

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(ANSWERS BY DR. BUEHLER)

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the Hospital other than nurses and doctors. That
is obvious?

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A. That is correct.

6

Q. And you didn't focus on
them?

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A. That is correct, we --

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Q. All right.

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A. We looked at information
relevant to others but not in nearly the amount of
detail that we used to look at physicians and
doctors.

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Q. And even in the nurses and
doctors that you looked at it is fairly clear from
your evidence in the past few days that you looked
at only certain groups of nurses and only certain
groups of doctors. You didn't look at all nurses
even amongst the people that were on on nights?

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A. Well, for physicians we
looked at those who -- initially for physicians we
looked at the call schedule for the Cardiology Ward.
Later for physicians the call schedule for the
entire Hospital was examined. For nurses we looked
at duty schedules for Wards 4A and 4B.

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Q. All right. And that is what



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(ANSWERS BY DR. BUEHLER)

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I am referring to as a pretty limited class of
nurses, the 4A and 4B nurses, because we know there
were other nurses in the Hospital that you didn't
look at.

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A. That is correct.

8

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Q. All right. And those were
other nurses in the Hospital at night. Am I right
on that?

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A. Yes.

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Q. All right. And obviously
the people that you looked at, the nurses and the
doctors, even using the information you had, you
looked at the people you expected to be there. Isn't
that right?

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Maybe my question should be
rephrased. You don't know anything about people
who may have been there who weren't expected to be
there because you don't have data about that. Isn't
that fair?

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A. Yes.

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Q. I hasten to add, and I want
this to be clear, if any of your colleagues disagree
with you -- I hear the calls from the wings or
the audibles from the sideline -- if they do disagree



CC8

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(ANSWERS BY DR. BUEHLER)

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with you please advise me or advise the Commissioner
on any one of my questions.

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All right then. To go back to the
information that you had when you started up this
investigation, I take it it was also very clear to
you (it was notorious in fact) that digoxin -- it
was something about digoxin that was giving people
concern. Is that fair?

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A. Yes, that is fair.

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Q. And you knew digoxin had been
raised at the preliminary inquiry as the alleged
medium that contributed to the deaths of these
children. Is that right?

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A. Yes. We were aware that that
issue had been raised.

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Q. And is it pretty fair to say
that your investigation really from the outset,
just looking at your terms of reference, assumed
that digoxin was at least the chemical agent. Is
that accurate?

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A. One of the questions that we
specifically asked -- first let me back up.

By very virtue of the issue of
post mortem digoxin levels in exhumed tissues and



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(ANSWERS BY DR. BUEHLER)

different types of other post mortem tissues and pre-mortem tissues, we were clearly in terms of our reference aware that there was a great deal of controversy surrounding the interpretation of that information. That was the reason we sought the assistance of Dr. Kauffman.

One of the questions we asked Dr. Kauffman to address -- clearly Dr. Kauffman's review was focused on digoxin, but we did ask him to address the issue of was his impression that there were other medications given which may have contributed to death and/or modified the response to digoxin.

Q. All right. I simply was trying to get at the point, and perhaps I am belabouring it, that digoxin was pretty much in the forefront of your minds when you went into this investigation?

A. That is correct.

Q. Now I mentioned to you that for reasons which you can well understand my client is vitally interested in your report, and my question to you is whether at any point any one of you or your team ever went to speak to my client during the



CC10

1 (ANSWERS BY DR. BUEHLER)

2 course of your investigation?

3 A. None of the members of this
4 team has ever spoken to your client.

5 Q. Were you under any instruction
6 from anyone not to speak to my client?

7 A. No.

8 Q. You never asked her or me if
9 you could speak to her, did you?

10 A. That is correct.

11 Q. So you obviously did not put
12 any questions to her about anything concerning her
13 procedures as team leader which might have contributed
14 to these deaths?

15 A. That is correct.

16 Q. Or anything that she might
17 have known about the procedures of any other person
18 that might have contributed to these deaths?

19 A. That is correct.

20 Q. Did you in the course of
21 your investigation look at any of the many, many
22 statements that my client has given to the Metro-
23 politan Toronto Police in this matter since the
24 inception of the investigation?

25 A. We have read parts of the
testimony that was given in the legal proceedings



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(ANSWERS BY DR. BUEHLER)

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following Nurse Nelles' arrest, but again I think --

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Q. Well, let --

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A. -- I think it is extremely

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important to emphasize as we have before that we
were not criminal investigators.

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Q. All right. I think that is

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a fair observation, and you have made that before.

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You don't see your function as

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either detectives or policemen, do you? Is that

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fair?

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A. We are certainly not policemen.

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Q. You may be detectives, but in

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a world that perhaps Quincy occupies, or maybe
Quincy is a bad example.

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A. I have never seen that TV

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show.

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Q. You are scientists, not

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detectives; is that fair?

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A. We try to approach this

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scientifically; correct.

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Q. And you obviously do not

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approach it as prosecutors either, do you?

23

A. That is absolutely correct.

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Q. And you wouldn't want to be

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(ANSWERS BY DR. BUEHLER)

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understood publicly to be either policemen or

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prosecutors?

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A. We wouldn't want our informa-
tion to be misused.

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Q. All right. I will come to
that in a moment, but just dealing with my initial
question: You mentioned you read some of the
evidence at the preliminary inquiry.

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My question was a bit more specific,
and that was, did you ever read any of the many state-
ments, and, there are well in excess of fifteen
statements my client has given to the Metropolitan
Toronto Police in this matter since its inception
in the course of the investigation, in the course of
the preliminary inquiry and subsequent to the
preliminary inquiry, and my question is whether you
have read any of those?

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A. The only information that we
would have read would have been in the transcripts.

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Q. Well, dealing with the
transcripts were you -- I take it you were aware that
my client gave evidence at the preliminary inquiry
for some five or six days? Were you aware of that?

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A. I was not -- I was aware that

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(ANSWERS BY DR. BUEHLER)

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your client gave testimony at the preliminary hearing.

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I had no idea how long she was on the witness stand.

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Q. All right. Did you read
her evidence, do you recall?

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A. I read quite -- I read some
of that testimony. Actually the testimony that I
read in greatest detail dealt with evidence presented
concerning levels of digoxin, and I may have read
some of your client's testimony but I don't remember
in particular.

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Q. How about your colleagues?
Do they recall reading my client's evidence?

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A. (Dr. Smith) I remember reading
some of it. I don't remember specifically anything
that I read at that time.

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Q. Dr. Wallace?

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A. (Dr. Wallace) Yes, I have
read some of her testimony.

18

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Q. Do you recall if you read all
of it or not?

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A. (Dr. Wallace) No, I have not
read all of it.

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Q. All right. Were you aware,
Dr. Buehler, that as of July 1980, my client had been

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(ANSWERS BY DR. BUEHLER)

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at The Hospital for Sick Children for two and a half
4 years?

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A. I don't remember if I had
been told how long she was there or not.

6

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Q. Dr. Smith?

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A. (Dr. Smith) I was not aware
that she had been there for any period of time.

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Q. Let me ask you, Dr. Buehler,
on the subject of epidemiologists and what they do,
what you people do when you are looking at an
epidemic.

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To take a typical epidemic situation
would one of the things that you would look for in
trying to pinpoint a cause of an epidemic be some-
thing new in the environment?

16

A. Yes.

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Q. Can you give us an example
of the sort of thing that you would look for?

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A. For example, if you were
investigating an outbreak of infectious disease in
a hospital you might look to see whether or not
there were changes in the way that disease is
diagnosed.

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Q. Changes in the way the disease



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(ANSWERS BY DR. BUEHLER)

is diagnosed? Would you also look perhaps for some new thing that has been brought into that hospital environment?

A. I think you could answer that question by looking at the steps that we took in approaching this.

We did attempt to get background information on the Hospital in terms of the types of procedure, et cetera, and we in the initial interviews that we had with Hospital personnel asked those kinds of questions.



Smith, Buehler
Wallace, Kusiak
cr. ex. (Strathy)

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DM/PS

(ANSWERS BY DR. BUEHLER:)

Q. Looking for something new?

A. We asked about, for example, were there any changes in the way -- we were aware for example that there was a new cardiology ward three months before this happened. We asked about, you know, were there more surgical procedures that lasted say longer than four hours; or was there more occupancy, etc., so we asked about that type of background information. I cannot say that we can conclusively prove that nothing new happened at the hospital in July, 1980. One of the things that does happen every July is a new set of doctors come on the ward.

Q. I'm sorry, a new set of doctors?

A. Yes, the academic year is usually July to July, so that is when physicians rotate their annual schedules.

Q. Well, the purpose of all these questions that you were asking, and the ones that you have just identified, that was for the purpose of seeing if there was some change at the outset of the epidemic period, is that right?

A. Yes, that is correct. Was



(ANSWERS BY DR. BUEHLER:)

there a change that occurred in parallel, and we attempted to use the available data to address that issue.

Q. That is something that I am interested in, because I have been unable to see, I see speculation in your report, maybe that is as far as it has got, as to why it was that this epidemic, as you call it, started in July of 1980, that is something that I don't understand.

Let me ask you, did you look at what was new in July of 1980, or the period of time, let's say, shortly before that, in terms of specific personnel?

A. No, we did not; in terms of nursing personnel are you asking?

Q. Let's start with nursing personnel. Did you look at the question of whether there were any new nursing personnel whose presence on the ward coincided with the time of the so-called epidemic?

A. No, I don't believe that we did that.

Q. Did you look at the presence of any non-nursing personnel, let's say, doctors,



Smith, Buehler
Wallace, Kusiak
cr. ex. (Strathy)

(ANSWERS BY DR. BUEHLER:)

to see whether that coincided.

A. We know from the physician call schedule that they change approximately once every four to six weeks; then we also know that physicians change for their academic year.

Q. Their new year starts in July?

A. Yes.

Q. So you know that. What about other personnel?

A. We did not inquire about changes, new personnel in other categories.

Q. Would it not have been of interest to you for you to know as epidemiologists whether there was a new nursing personnel that were on the ward at the commencement of the period?

A. The types of changes we were interested in were more dealing with routines for patient care, and indicators of patient care. Again, I think you are beginning to potentially push us to the limit of what you might describe as the boundary, or where epidemiology may end and other types of investigations may begin.

Q. So are you suggesting that this



(ANSWERS BY DR. BUEHLER:)

question of what new personnel appeared on that ward in July of 1980 may be an interesting question for a detective, but not for an epidemiologist, is that what you are saying?

A. That was not a question that we asked.

Q. All right. Are you suggesting it might be a germane question if one were trying to find an explanation for the epidemic?

A. I probably should not try to recommend to others how they conduct their investigation.

Q. In any event, we know it is not something you did.

A. That is correct.

Q. Well, now, one of the things that you mentioned you did in your report, and I am not sure that I have the page reference, but I recall that you asked when you were dealing with the hospital personnel, you asked for a list from the physicians, I believe, of any residents, perhaps it is fellows who had experienced difficulties during their period at the hospital; do you recall that in your report?



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2 (ANSWERS BY DR. WALLACE:)

3 A. (DR. WALLACE) That is
4 contained on page 20 of the report, yes.

5 Q. Yes, thank you. It is in the
6 first paragraph of page 20 and it says:

7 "In addition, the Director of
8 Medical Education was asked to provide
9 a list of house staff physicians
10 who had encountered problems during
11 their training years, and the schedules
12 of these individuals was scrutinized."

13 I take it then that you did have a list of house
14 staff physicians who had encountered problems, is
15 that right?

16 A. We didn't have a list. This
17 was a verbal communication to myself from Sister
18 Kenny, who is with the Medical Education Department.

19 Q. What did you mean by:
20 "...problems during their training
21 period."

22 What were you talking about there?

23 A. When it was decided to look
24 at nursing and physician schedules in detail,
25 and we found data for the physician schedules
to be inaccurate and incomplete, I went and I



(ANSWERS BY DR. WALLACE:)

discussed the whole matter with Sister Kenn who is responsible for drawing up many of these schedules. At the time I asked her if there had been individuals in the resident staff who had experienced difficulties of any sort in the time they were employed at the Hospital.

Q. Now just dealing with your particulars, would you agree with me that when you used the word "association", and in particular when you used the word "association" in your report, you are not talking about cause, is that fair?

(ANSWERS BY DR. BUEHLER:)

A. That is correct.

Q. Is that a fairly fundamental tenet of epidemiology, that association is not cause?

A. Yes, that is correct.

Q. Your colleagues are nodding their heads, I would think that is sort of basic first year epidemiology, is that true?

A. That is correct.

Q. And in your report, is it fair to say that you do not purport, when you talk of



(ANSWERS BY DR. BUEHLER:)

associations, to be talking of cause, is that so?

A. That is correct. There is one place in the report where we use the word "cause" and I said yesterday that was an unfortunate choice of words.

Q. So in terms of people looking at your report, and hearing your evidence, would it be fair to say that you would caution strongly about someone equating association with cause, you would caution against that?

A. Yes.

Q. And you would certainly not want to be interpreted by anybody to be suggesting that association in the case of your lists can, should or ought to be linked with cause, is that fair?

A. In the report there is a section where we did speculate. I think it is not unusual in investigations where there is incomplete data to offer speculation, but clearly we would not want anyone to conclude that because we observed an association between the presence of a particular individual and deaths, we would not want anyone to conclude that we say there is a causal



(ANSWERS BY DR. BUEHLER:)

relationship.

Q. And as you said when Mr. Shanahan, who was the previous counsel, when he was asking you questions I think you recognized that there is a danger that the sort of information contained in your report may be misused by people who do not appreciate the limitations of what you have said in your report, is that fair?

A. It is certainly possible that the information in our report could be misused by someone.

Q. And certainly as a scientist, obviously you would not want it to be misused, and you would want to have people recognize the limitations which you put on it.

A. I believe that in our report we would not want people to overstate our findings, or understate our findings as the Commissioner has added.

THE COMMISSIONER: I think overstate is probably right there. Would this be a good time?

MR. STRATHY: Yes, it would, Mr. Commissioner.

THE COMMISSIONER: All right, we will take 15 minutes.

---Short recess.



BM/ak

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3 --- Upon resuming.

4 THE COMMISSIONER: Yes, Mr. Strathy.

5 MR. STRATHY: Q. Yes. I wonder
6 if you would turn to Tab 2 of your report, which
7 is entitled, at least in the copy that I have Nurses
8 Code.

9 (ANSWERS BY DR. BUEHLER)

10 A. May we have another copy.
11 We are working from original versions. This coding
12 book was collated separately.

13 Q. Now, what I would like to
14 understand is who was included or who was given
15 a code number?

16 (ANSWERS BY DR. SMITH)

17 A. Anyone who was on duty at
18 any time during the epidemic period.

19 Q. On duty?

20 A. On duty on Wards 4A or 4B
21 and appeared in our data sources was given a code
22 number.

23 Q. So, the people we look at on
24 these four pages are 4A or 4B nurses.

25 A. They are nurses who worked
on 4A or 4B. They are not what we have referred
to as 4A/B nurses which would be the teams.



(ANSWERS BY DR. SMITH)

Q. All right. They may include then people who, although not regularly assigned to Ward 4A and 4B, worked on occasion in those wards during the epidemic period.

A. Correct.

Q. Now then I take it they do not include the non-4A, 4B nursing personnel who worked on other floors but did not, at least as far as you could tell, come to 4A and 4B during the period?

A. That is correct.

Q. In other words, there may have been other nurses working in the Hospital for Sick Children, in fact I am sure there were other nurses working in the Hospital for Sick Children during the epidemic period assigned to other floors who, as far as you could tell, never did come to 4A and 4B.

A. That is correct. If the name was not listed in our data sources which we described earlier their names would not have been coded and they would not appear on this list.

Q. That is not to say of course that they did not come to 4A and 4B at any time or



(ANSWERS BY DR. SMITH)

times during the epidemic period, is that right?

A. Do you mean to visit or to work?

Q. Well, let's say to visit. Let's go back to your data sources. As I understand it it was the 4A, 4B schedule book, workbook.

A. The schedule book and the payroll sheets.

Q. So, the people that as far as you know were on 4A and 4B were people who were slotted there by the Hospital.

A. That is correct, officially slotted there.

Q. But you cannot rule out the possibility that some nurse assigned to another floor came on the ward to visit at any time or times during the epidemic period?

A. Absolutely, yes.

Q. And you didn't even look at the data - well, there was no data on that, so, you couldn't look at it?

A. There were no data to examine, no.

Q. Well, I am interested in the



1
2 (ANSWERS BY DR. SMITH)

3 nurse supervisor or the supervising nurse. I know
4 the subject was raised with you yesterday but I
5 would like to pursue it a little bit further. Am
6 I right that the nurse supervisors are not listed
7 on this four page list?

8 A. I'm not just sure if they
9 are here on this list or not.

10 (ANSWERS BY DR. BUEHLER)

11 A. If for example the nurse
12 supervisor appeared on the payroll sheet as being
13 temporarily assigned to the ward it is possible that
14 a nurse supervisor would appear on our log if such
15 an event occurred. But you are correct in stating
16 that we did not include in the calender per se the
17 nurse supervisors.

18 Q. All right. So, this calendar
19 that was prepared by Nurse Shilton, I believe her
20 name was.

21 (ANSWERS BY DR. SMTIH)

22 A. Yes.

23 Q. Did not include the nurse
24 supervisors?

25 A. Not unless they were
specifically assigned to the ward and listed in



1
2 (ANSWERS BY DR. SMITH)

3 our data sources.

4 Q. Well, as I understand it
5 the nurse supervisors were not the sort of people
6 that were specifically assigned to 4A and 4B, isn't
7 that right?

8 A. That is my understanding as
9 well, yes.

10 Q. So that there were these
11 nurse supervisors who were, as a matter of routine,
12 in the Hospital at night who are not part of the
13 Shilton study and therefore you have no mapping of
14 their movements, is that right?

15 A. We have no mapping of their
16 movements.

17 Q. Do you know incidentally how
18 many nurse supervisors were on each night?

19 A. I don't.

20 Q. My information is that
21 there were two.

22 (ANSWERS BY DR. WALLACE)

23 A. It was my understanding that
24 there were three but I may be in error.

25 Q. Do you know the source of
your understanding; in other words, how do you know
there were three or can you help us there?



1
2
3 (ANSWERS BY DR. WALLACE)

4 A. I can't remember the source
5 of that information.

6 Q. And is it your understanding,
7 Dr. Wallace, that these nurse supervisors were on
8 in effect throughout the nighttime period?

9 A. Yes, I believe that to be
10 true.

11 Q. Do you know when they came on
12 shift?

13 A. No, I'm sorry I do not.

14 Q. Well, the Commissioner asked
15 you, Dr. Buehler, yesterday at page 559 of the
16 transcript in the course of your questioning by
17 Ms. Symes about your, his words were:

18 "THE COMMISSIONER: Would it not
19 concern you if a supervising nurse
20 was, or by coincidence happen to be
21 on duty at the time of all of these
22 deaths?"

23 And you said:

24 "DR. BUEHLER: Yes, that would be
25 a concern."

Do you recall your evidence on that?

A. (Dr. Buehler) I am not



(ANSWERS BY DR. BUEHLER)

reading from the transcript right now.

Q. That is page 559 about the middle of the page.

A. Yes, that is correct.

Q. But then you went on to say:
"DR. BUEHLER: We did not address the issue of the supervising nurses."
Do you see that?

A. That is correct, we did not have a 24-hour calendar for the supervising nurses.

Q. So, it is not something on which you have data?

A. That is correct.

Q. But you would agree with me I think that if one was doing a complete sort of association study that is data that you would ideally like to have.

A. There is a great deal of data that if we were going to be 100 per cent complete would be ideal to have. I think we emphasized before that we focused on doctors and nurses who were on duty for prolonged periods on the ward.

Q. Well, let me put it to you



1
2 (ANSWERS BY DR. BUEHLER)

3 this way. If you were to be satisfied that one of
4 the nursing supervisors was present on 4A and 4B
5 for, let me use the word, a significant number of
6 the Category A and Category B deaths, would that
7 be something of interest to you?

8 A. I think that it would be
9 important to look at that in terms of the relative
10 risk estimates, as we have done with the other
11 nurses if we are going to look at it in that way.

12 Q. Well, let me be a bit more
13 specific. Supposing you were to ascertain that a
14 particular nurse supervisor, and let's just take one
15 for the moment, but a particular nurse supervisor
16 was present on the ward for let us say 20 of 28
17 deaths, would that be a matter of interest to you?

18 A. I think you would need to
19 compare that to the other nurse supervisors.

20 Q. All right. Let's suppose
21 that there were two nurse supervisors who were
22 present on the ward for 20 of 28 deaths, would that
23 be of interest to you?

24 A. One thing we did not do in
25 our analysis of the data was to look at combinations
of two or more personnel, that was not an analysis



1
2 (ANSWERS BY DR. BUEHLER)

3 that we performed.

4 Q. Well, I understand the
5 limitations of where you went in terms of pairing
6 personnel.

7 A. Yes.

8 Q. But I am just putting to you
9 this hypothetical situation of a nurse supervisor ---

10 Excuse me, Mr. Commissioner, just for
11 the information of counsel who perhaps may not be
12 used to our procedures I think it is best that if
13 counsel has an objection that it be raised rather
14 than communicating to the witness.

15 MS. NESLUND: Yes, I have an
16 objection to him propounding hypotheticals to
17 Dr. Buehler.

18 THE COMMISSIONER: I'm sorry,
19 what was that? Would you not be interested? That
20 is not quite a hypothetical, it is the manner in
21 which they conduct their investigation.

22 MS. NESLUND: He got into an
23 area, he started an area that was a gray area and
24 then made the hypothetical, actually, formulated a
25 pretty strong hypothetical. It would call on
Dr. Buehler to actually get into an area that would



1
2 be beyond the scope of his expertise.

3 THE COMMISSIONER: No, no, he is
4 an epidemiologist. The question is, would he as an
5 epidemiologist be interested if the facts that he
6 found by examination that a supervisor was on the
7 scene, at least in the wards at the time of the
8 deaths, we will say 20 out of the 28 suspicious
9 deaths. That is the question and I would have
10 thought that that is in his field of expertise
because he is an epidemiologist. No?

11 MS. NESLUND: My interpretation of
12 the rules would be contrary to that. The rules are
13 that he is not permitted to give expertise
14 testimony in that area. We have discussed this
15 before that it does get into many gray areas. I
16 think probably Dr. Buehler handled the question just
17 fine but perhaps my feeling would be that Counsel
18 just avoid when possible getting into -- you see,
19 it puts Dr. Buehler into the position, not that
20 we want to be disruptive, it puts him in the
21 position of violating the Public Health Service
rules.

22 THE COMMISSIONER: Well, I'm sure
23 you are much more familiar with the rules than I am
24 but he is here as an expert epidemiologist and I
25



1
2 thought that that was what his question was leading
3 to, that expertise. The minute of course they start
4 saying if a child displayed these symptoms would
5 he appear to be suffering from digoxin toxicity or
6 something like that then that is obviously a
7 breach of the rules that I can understand but I
8 don't understand...

9 MS. NESLUND: The rules actually
10 get into areas of epidemiology as well that he
11 cannot speak as an expert in this proceeding from
12 that field. I realize many of the questions - we
13 realize it is hard to draw the line and I am well
14 aware of that and in most instances we have just ---

15 THE COMMISSIONER: Well, perhaps we
16 can solve this problem by Dr. Smith or Dr. Wallace
17 coming to the rescue under these circumstances.

18 MS. NESLUND: I think that would
19 be the easiest.

20 THE COMMISSIONER: We don't want
21 you to go home and get into trouble with the powers
22 that be, whereas, I can perhaps protect Dr. Smith
23 and Dr. Wallace.

24 MR. STRATHY: Maybe Dr. Buehler can
25 hold up one hand if he agrees and two hands if he
disagrees.



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2
3 Q. Well, all right, Dr. Smith,
4 let me put the question to you and if you would
5 prefer that Dr. Wallace answer please let me know.
6 But let me go back and rephrase my question. Let
7 me start with a question that puts to you that a
8 nursing supervisor was present in the Hospital
9 and was associated with the deaths to the extent
10 of 28 of 28 Category A and Category B deaths.

(ANSWERS BY DR. SMITH)

11 A. 28 of 28?

12 Q. Yes, let me put that to you
13 to start with. Now, I take it that that would be
14 a matter of ---

15 MS. SYMES: Excuse me, I presume
16 that this is a hypothetical if?

17 MR. STRATHY: Well, I haven't
18 heard any evidence yet but I think I am entitled
19 to put hypotheticals.

20 MS. SYMES: No, it is just that
21 the statement didn't include an "if".

22 MR. STRATHY: Well, I thought it did.

23 THE COMMISSIONER: I thought -
24 well, he started saying "Let us assume", which is
25 much the same.

MS. SYMES: All right.



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MR. STRATHY: Q. My question then, Doctor, is whether that would be a matter of significant interest to you as an epidemiologist?

(ANSWERS BY DR. SMITH)

A. The simultaneous occurrence of a presence of a supervisor and one of the 28 deaths.

Q. No, 28.

A. And 28 of the 28 deaths would be of some concern. However, the calculations with which we would compare that particular nurse would have to be done in a similar fashion to the calculations which were done for the presence or absence and to get at the particular association of each individual nurse and then we would have to compare those.

Q. Of course. But assuming that the methodology adopted was the same and that the methodology adopted didn't differ at all from the methodology you have previously applied. I am sure you would agree with me that that would be of interest to you in this particular case.

A. That would be of some interest, yes. An additional situation would be that the actual time on the ward would have to be taken into



(ANSWERS BY DR. SMITH)

consideration for that supervisor.

Q. Well, except for this fact that for the supervisor you wouldn't necessarily know when she would be in 4A and 4B because, as I understand it, they are the type of people who might come up at any time. Isn't that so?

A. I understand that they circulate through the Hospital, yes..

Q. Exactly. So, for a supervisor you may have no precise record as to when the supervisor was or was not on 4A and 4B?

A. We would not have a precise record.

Q. But I suggest to you that the very presence of that individual within the Hospital and the association between that individual's presence and the particular deaths would be a matter of interest to you?



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FF (ANSWERS BY DR. SMITH)

EMTrc 3

A. It would be of interest.

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Q. All right. And that again --

5

one hand or two hands, doctor?

6

THE COMMISSIONER: The reason I mentioned it yesterday, it seems to me relatively easy at least to determine whether a particular supervisor was on duty, not whether she was on Ward 4A and 4B, on duty in the Hospital on the night of all of the deaths.

10

11

That sort of thing I think could have been determined, could it not? I mean there must be records of what supervisors are on duty, and I take it you did this for the doctors and for Ward 4A?

12

13

14

15

DR. SMITH: Yes.

16

17

18

19

THE COMMISSIONER: And doctors who are on duty in Ward 4A generally I suppose don't go -- at least junior doctors don't go moving to another ward?

20

21

22

DR. SMITH: No, they just attend wards to which they are assigned.

23

24

25

THE COMMISSIONER: And the nurses just attend on the ward to which they are assigned?

DR. SMITH: That is right.



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THE COMMISSIONER: But the supervisors have the whole Hospital, and there may be perhaps less suspicion -- I don't know if that is true or not, but at any rate the opportunity to be associated, if not the association, would be there for... I would suspect that information could still be obtained. I may be wrong.

DR. SMITH: Yes, I would think that would be obtainable.

MR. STRATHY: Well, that is information I would like to ask for, Mr. Commissioner.

THE COMMISSIONER: Well, I don't know how -- is there some way, Mr. Roland? Were you listening to this?

MR. ROLAND: Well, I don't have it with me.

THE COMMISSIONER: No, no, no.

MS. CRONK: The very first time!

MR. ROLAND: We will see what we can do.

THE COMMISSIONER: All right. Thank you. But I don't think we need to put you to any problem unless it turns out that there is a supervisor --



Smith, Buehler
Wallace, Kusiak
cr.ex. (Strathy)

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MR. STRATHY: Well, I would like to pursue the matter at least briefly, Mr. Commissioner.

THE COMMISSIONER: All right.

MR. STRATHY: Q. And ask a further question, Dr. Smith, and let's say that again using the same methodology that you used with respect to the other nurses you were to find that a particular nursing supervisor was associated with let us say between 20 and 25 of these deaths. Would you agree that that would also be of interest to you as an epidemiologist?

(ANSWERS BY DR. SMITH)

A. It would be of interest, but I repeat the actual calculations would have to be performed to put the rate -- to put the relative risk of that individual into some perspective.

Q. All right. But --

A. (Mr. Kusiak) Can I add --

Q. I will give you a moment, Dr. Kusiak --

A. (Mr. Kusiak) Mr. Kusiak.

Q. Mr. Kusiak.

But, Dr. Smith, assuming that you have the information and assuming that you do the calculations you would agree the results may be of interest to you?



FF4

(ANSWERS BY DR. SMITH)

A. They could be of interest.

THE COMMISSIONER: I take it there would be some circumstances when you wouldn't bother, and perhaps I am addressing Mr. Kusiak for this, but presumably if there were no supervisor who was on duty for more than two or three of the deaths it wouldn't be worthwhile even bothering with the calculations?

DR. SMITH: One could go through a process of elimination and not actually have to do all of the work.

MR. KUSIAK: The only comment I would offer is that the interpretation would be slightly different since the data would not be the same as the nursing schedule in the sense that the location for the nursing supervisor wouldn't necessarily be 4A/4B.

MR. STRATHY: Q. Yes, but the location itself would be The Hospital for Sick Children?

(ANSWERS BY MR. KUSIAK)

A. Yes, that is true, so there is a slight difference between that and the nursing schedule.



FF5

(ANSWERS BY MR. KUSIAK)

Q. But again while that does not in and of itself indicate that that person was actually present on 4A and 4B, it does indicate that at least there was the opportunity for that person to be present?

A. Quite true.

Q. And again perhaps I can go back to Dr. Buehler.

Now would you agree with me if we are able to obtain this information concerning nursing supervisors and if it does establish an important, let us say, significant relative risk concerning the nursing supervisor's presence and the particular deaths, would you agree that its absence may be a significant shortcoming in your report; not necessarily that it is your fault but that it is a significant shortcoming?

(ANSWERS BY DR. BUEHLER)

A. I think we have made it clear that we didn't look at all the people who were in the Hospital and --

THE COMMISSIONER: I wonder if I could just suggest that Mr. Strathy put his question a little more politely by saying that its addition



FF6

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(ANSWERS BY DR. BUEHLER)

3

might improve your report.

4

MR. STRATHY: All right. That is a fair way. I will put it that way.

5

6

Q. Would you agree in the case of these nursing supervisors the addition of that information might improve your report?

7

8

A. The addition of that information would certainly increase the comprehensiveness of our report.

10

11

Q. And indeed I have picked the nursing supervisors, and we will deal with the evidence on that point, but you will acknowledge that there may well be other individuals in the Hospital for whom you are not able to give us associations simply because you had not the data?

12

13

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16

A. That is correct, and I believe that is something that we make clear in our report.

17

18

Q. All right. Let me take you to a different subject, and I would like to ask you about epidemiological investigations.

19

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I have in front of me Exhibit 325 which is the single page. Is this, Dr. Smith, is this your outline?

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23

(ANSWERS BY DR. SMITH)

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A. Yes, that is a brief outline --

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FF7

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(ANSWERS BY DR. SMITH)

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Q. All right.

4

A. -- that I prepared for Mr.

5

Lamek.

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Q. Just looking at the middle of the page you indicate Step No. 1 is define the problem (case definition), and am I correct if we are going back to our first year epidemiology course that that is the starting point for virtually every epidemiological investigation, to define the case?

12

13

14

A. That is correct. That is a first point, and we do make a reference in the report to the fact that we could not formulate a case definition strictly on toxicological grounds.

15

16

17

18

Q. All right. So that in view of the nature of the problem that presented itself you were not able to define the case perhaps in traditional epidemiological terms; is that fair?

19

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A. We could not give an exact definition, case definition.

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Q. All right. And indeed the definition of the case itself appears to fluctuate depending on whether you are dealing with Category A, Category B or Category C. Is that fair?



FF8

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(ANSWERS BY DR. SMITH)

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A. Those are not case definitions

4

as such.

5

Q. All right. What are they?

6

A. Well, I would define them

7

as just particular categories that were put together

8

for the purpose of grouping deaths in the periods

9

which we were studying.

10

Q. Let me go about this --

11

A. One could group them in many

12

ways, and those were arbitrary categories in which

13

we chose to group them.

14

Q. Let me go about this a

15

different way to make sure I understand it.

16

When you talk about defining the

17

case, and let me pick an example, Dr. Smith, I

18

believe you have had experience with lung cancer;

19

part of your research is in lung cancer. Is that

20

right?

21

A. Part of my research is,

22

which I listed in my vitae, developing a proposal

23

for case control study of lung cancer. That is not

24

complete.

25

Q. Dealing with that in a

typical epidemiological investigation you would start



FF9

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(ANSWERS BY DR. SMITH)

3

with a definition of the case in terms of lung

4

cancer; is that fair?

5

A. You would start with that,

6

yes, and you would make some specific criteria to

7

what constitutes a case of lung cancer.

8

Q. And if Dr. Buehler was looking

9

at gastroenteritis or conjunctivitis he would do

10

the same thing.

11

Am I right that you would define

what it is you are talking about in medical terms?

12

A. (Dr. Buehler) I have done

13

that in outbreaks of gastroenteritis and conjunctiv-
itis.

14

Q. Okay. That is why I used

15

those examples.

16

Now in this particular case, though,

17

as I understand it, Dr. Smith, you weren't able to

18

define a case in those precise terms because the

19

cases themselves were not capable of being defined

20

in strictly medical or toxicological terms. Is that

21

fair?

22

A. That is correct. We could not

23

define a single case. We had to really go at the

24

whole population and see how that could be broken

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FF10

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(ANSWERS BY DR. SMITH)

down.

A. (Dr. Buehler) Could I inter-
ject there? I believe you are addressing the
comparison of epidemic period deaths to deaths in
other periods.

Q. Well, actually to tell you
the truth I am not, so I think it would be best if
you not anticipate where I am going because I am
not going in that direction unless you want to make
some comment about the subject.

A. (Dr. Buehler) Excuse me.

Q. Okay. Now then, Dr. Smith,
carrying on, after the definition of the case do you
then go out and look at the cases? Is that what
you do in epidemiology? You say, all right, who is
it out there that has got lung cancer in the
community you are looking at?

A. Yes. Well, we define -- yes,
if we have a case definition we would look for that
case definition in the population.

Q. All right. You define what
it is you are looking for.

A. That is right.

Q. You look at the population



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FF11 2

(ANSWERS BY DR. SMITH)

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and you say who fits within this case definition;

4

is that right?

5

A. That is correct.

6

Q. And is there a stage there

7

once you start looking at the population in which

8

you verify your diagnosis? You satisfy yourself

9

that indeed this is a case of gastroenteritis and

10

A. You try to comply with the

11

criteria which were set out to define the case.

12

Q. And you make sure that the,

13

call them specimens or subjects that you are looking

14

at are in fact true cases?

15

A. That is called ascertainment.

16

Q. Ascertainment. So can we

17

take a step, define the case, verify diagnosis,

18

ascertainment. Is that three steps or just two

19

steps?

20

A. It is really two steps. You

21

ascertain that the criteria have been properly met

22

and that that is indeed a case.

23

Q. So that what you are looking

24

at is in fact the thing that you want to investigate

25

and not some other thing?



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FF12 2
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(ANSWERS BY DR. SMITH)

A. That is correct.

Q. And then once you have done that, once you are satisfied that you have got true cases, that is the point at which you start moving on determining if there is an epidemic and looking for the type of associations that you have talked about already?

A. Yes.

Q. Is that right?

A. That is correct.

Q. And presumably the whole process of this verifying the diagnosis and the ascertainment is to make sure that you are not leading to false associations by including untrue cases in your sample; is that fair?

A. Yes, it is important to include true cases in the sample or to define -- yes, you are correct.

Q. Because if you presumably include in your sample things that are not true cases you may as a result have false associations as a result; is that fair?

A. You may have an inappropriately higher incidence of so-called cases.



FF13

(ANSWERS BY MR. KUSIAK)

Q. And indeed you may also have false associations because you are not dealing with gastroenteritis; you are dealing with gastroenteritis and appendicitis so the associations you get may be misleading?

A. You are suggesting that the number of cases would be contaminated with people who are in fact not cases.

Q. Thank you. That is --

A. And the effect of that would then be to somehow make it more difficult to see association between the case that you are actually looking for and the factors that cause that case.

Q. Yes. It may not only make it more difficult but the associations that you get may be inaccurate.

A. They would be inaccurate and also tend to be less strong.

For instance, if I had 100 cases of gastroenteritis and somehow contaminated with that were 500 other cases then the 500 other cases would be unrelated entirely to the risk factors that caused the gastroenteritis and therefore statistics would



FF14

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(ANSWERS BY MR. KUSIAK)

3

probably come up with a risk factor somewhat lower.

4

Q. Well --

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A. You wouldn't be able to

6

detect the risk factor that is associated with the cases you defined.

7

Q. All right. But let me go

8

back. I am not sure I remember your words, but,

9

yes, I am suggesting that the result of including

10

things that are not true cases in a sample might

11

result in a -- well, incorrect results.

12

A. Yes, and one could even go

13

a little bit further and say that the incorrect

14

result, you know, if one did the usual statistical

15

test associations, that the associations would not be as strong as they really should be.

16

Q. Well, except that there may

17

be associations between your not true or untrue

18

cases and also with your true cases, and they may

19

be common associations, so there may be as strong

20

or stronger associations?

21

A. If I found in an epidemio-

22

logical study that one factor was both related to

23

one case, a case and a non-case, I would reject that

24

as being an agent or variable that could possibly

25



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FF15 2 (ANSWERS BY MR. KUSIAK)

3 be causative in the outcome that we were interested
4 in.

5 Q. Possibly, but not necessarily
6 because we have already heard that an association
7 is not cause?

8 A. That is true, and of course
9 I deal in probabilities so I can say nothing with
10 absolute truth.

11 Q. All right. But my point is
12 this, and I hope I am right in understanding at
13 least what it is that you are saying is that the
14 classical starting point is to make sure that you
15 are in fact dealing with apples and not apples
16 mixed with pears? Is that a crude way of putting it?
17 (ANSWERS BY DR. SMITH)

18 A. I am not sure that I under-
19 stand that analogy.

20 Q. Well then let me put it this
21 way: That you are in fact looking at the disease
22 you are interested in and not the disease mixed
23 with some other disease?

24 A. Yes, it would be ideal to
25 have a case definition and individuals who met that
case definition used only in the description of an
incidence curve, an epidemic curve. That would be
ideal.



1 (ANSWERS BY DR. SMITH:)

2 Q. And to be clear, then, the
3 case that you used in this investigation was
4 not a case that said you would look at babies who
5 died due to digoxin toxicity, that was not the
6 case, was it?

7 A. (DR. SMITH) We did not start
8 out that way. We started out defining the epidemic
9 curve, because we did not have a specific
10 toxicologically associated case definition. We
11 started out by defining death as that end point
12 that we would look at.

13 Q. All right. In effect, you
14 looked at death on Wards 4A and 4B in the Hospital
15 for Sick Children during the period July, 1980 to
16 March, 1981.

17 A. We looked at deaths for the
18 period preceding that and the period after that,
19 in other wards as well as are described in the
20 report. I will give you one of the graphs where
21 we actually looked at death.

22 Q. All right.

23 A. We defined our end point from
24 the description of those graphs as mortality.

25 Q. Can you give us that graph,
please?



(ANSWERS BY DR. SMITH:)

A. Mortality rates, that would be Figure No.4, and Figure No. 3 would be 4A/B deaths, these are the mortality rates.

Q. Well, to be clear, you defined your case simply in terms of the end result, is that right, in terms of deaths?

A. That is correct.

Q. And you did not define your case in terms of deaths due to digoxin administration?

A. We could not do that.

A. (DR. BUEHLER) May I ask which part of the study you are asking about, because it is important to speak to it.

Q. Ultimately we get down to the A, B, C categories, and we know how these are defined, and even those are not defined in terms of babies who died of digoxin intoxication, is that correct?

A. (DR. SMITH) They are defined as they are described in the broad categories that are described.

Q. Let's go to those, then.

A. On page --



1 (ANSWERS BY DR. SMITH:)

2 Q. Page 13.

3 A. Page 13.

4 Q. All right. What your
5 consultants were attempting to do, as I understand
6 it, at least, was not say this is a baby that died
7 of digoxin intoxication; they were attempting to
8 weight each child on a variety of scales, some of
9 which may have been related to digoxin intoxica-
10 tion, but were not necessarily definitive of digoxin
intoxication, is that correct?

11 A. Could you repeat that question?

12 Q. As I understand what your
13 consultants did, they were attempting to rate each
14 child on a scale, or in accordance with certain
15 criteria, some of which had to do with digoxin
16 intoxication, but they were not purporting to say
17 that any particular child died as a result of
digoxin intoxication.

18 A. I would have to preview the
19 actual testimony that Dr. Kauffman gave to be able
20 to answer that, I am not quite sure.

21 Q. Let us leave aside Dr. Kauffman's
22 testimony and simply look at the categories which
23 you have used in your report, based on the informa-
24 tion which you got from your consultants. As I
25



(ANSWERS BY DR. SMITH:)

understand it, none of those consultants in what they were doing was trying to say that a child did or did not die of digoxin intoxication.

For example, the cardiologist was asked whether the death was expected or unexpected and whether it was consistent with the child's clinical status, that in itself does not address the question of digoxin intoxication.

A. That is correct.

A. (DR. BUEHLER) That is correct.

Q. So that when these lists were being put together they are not lists of children who died of digoxin intoxication, is that correct?

(ANSWERS BY DR. BUEHLER:)

A. They are children who had those particular scores by the consultants.

Q. But within any of those categories, and let us simply take the category A deaths, there well may have been children whose deaths were natural and unrelated to digoxin intoxication, notwithstanding that they were scored as they were? If that is a medical question that you would rather not answer, I can understand that.

A. I think it would be best if



(ANSWERS BY DR. BUEHLER:)

Dr. Nadas could speak for himself on that issue.
I understand Dr. Nadas will not be providing
testimony at this proceeding.

Q. That is what I was concerned
about.

A. Those are the scores that Dr. Nadas
gave us as his clinical impressions based on the
pattern of the child's death, as a clinician, did
he think that the timing was unexpected, or that
the pattern suggested digoxin toxicity?

Q. But he was not purporting to
say, as I understand it, and as I understand your
report, that a particular child's death was caused
by digoxin intoxication.

A. That is quite correct.

Q. So are you prepared to take that
step and agree with me that any particular child,
in let us say category A, may or may not have died
of digoxin intoxication, that is really a matter
for the experts, I suppose.

A. This is a very important point.
Nowhere in the report did we say that a child died
because of digoxin intoxication. We merely give
levels of probability based on, particularly on Dr.



(ANSWERS BY DR. BUEHLER:)

Kauffman's scores, his 1 to 5 scale, was based on Dr. Nadas' clinical impression. Or, as you might have noticed, based on pathologist's scores as well. We did not only report, say, that this child died because of digoxin intoxication.

Q. And to go back to what we were discussing earlier, I take it you would not want it to be understood that any of the children, let us just stop at the category A deaths, you would not want it to be understood that any or all of those children necessarily died as a result of digoxin intoxication, because that is not what that addresses.

A. Based on our report we would not want anyone to conclude that we said that somebody died because of digoxin intoxication.

Q. Is that fair from all the witnesses?

A. (DR. SMITH) I would agree with that.

THE COMMISSIONER: Whenever it is appropriate.

MR. STRATHY: This would be convenient, sir.



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THE COMMISSIONER: Could you give us
some indication?

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THE COMMISSIONER: Quite possibly a
bit more, did you say?

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MR. STRATHY: I doubt that I will go
beyond the break.

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THE COMMISSIONER: No.
That's fine, no, no, you take what-
ever time you want. It is just about the scheduling.

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MS. CRONK: For the benefit of
other counsel, Mr. Commissioner, we will make suitable
arrangements with Ms. Symes' continuing cooperation
to have Ms. Costello here at the morning
break anyway.

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THE COMMISSIONER: Yes, I think so,
because certainly -- well, I would like to start
her unless this examination goes into tomorrow
afternoon and there would be no point, but I don't



1
2 it will.

3 MS. CRONK: Thank you, sir.

4 THE COMMISSIONER: Until 10:00
5 tomorrow morning; but you naturally won't have to
6 stay, you will not have to be here for any other
7 witnesses that come along, but there is no way we
8 seem to be able to get out. So, until 10:00
9 tomorrow morning.

10 ---Whereupon, at 4:30 p.m. the hearing adjourned
11 until Thursday, the 26th day of January at
12 10:00 a.m.
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